1/95

28/9,K/2 (Item 2 from file: 15)
DIALOG(R)File 15:ABI/Inform(R)

00972581 96-21974
McNeil data falsification alleged
Dickinson, James G
Medical Marketing & Media v30n1 PP: 19-20 Jan 1995 CODEN: MMKMBX ISSN: 0025-7354 JRNL CODE: MMM
DOC TYPE: Journal article LANGUAGE: English LENGTH: 2 Pages
WORD COUNT: 334

ABSTRACT: According to a citizen's petition by attorney Allen T. Eaton, over 30 years ago McNeil Pharmaceutical conducted a prolonged and successful effort to hide liver damage data about chlorzoxazone (Paraflex and Parafon Forte DSC) from the FDA .

TEXT: Back in the days when FDA only took two months to **approve** a new drug and **approval** was **automatic** if the agency delayed past the statutory **deadline** (pre-1962), McNeil Pharmaceutical conducted a prolonged and successful effort to hide liver damage data about chlorzoxazone (Paraflex and Parafon Forte DSC) from the agency, alleges a recent citizen's petition by Washington attorney Allen T. Eaton. McNeil is currently seeking to market the muscle-relaxant over-the-counter, a process that Eaton's petition is likely to frustrate. According to the petition, which seeks a marketing ban on chlorzoxazone, the drug is a close chemical relative of an earlier McNeil product, Flexin (zoxazolamine) which the company was forced to remove from the market in 1961 because of hepatotoxicity. Although aware of this similarity and of clinical results implicating chlorzoxazone in liver damage, McNeil falsified scientific data in order to withhold such information from its 1956 NDA for the drug, and later the company rewrote a purportedly independent clinical study report to assert "no hepatotoxicity," Eaton alleges.

The rewritten study was published under an outside investigator's name and appeared in the Pennsylvania Medical Journal. McNeil distributed it worldwide to establish in the professional community that chlorzoxazone was not hepatotoxic, the petition says. Over the years since, McNeil strenuously resisted all FDA efforts to strengthen liver damage warnings in the drug's labeling, and in 1978 FDA apparently gave up trying. Inspired by Eaton's role as plaintiff's attorney in successful civil litigation against McNeil over chlorzoxazone hepatotoxicity, the petition reads like a worst-case example of why FDA needs more clout over industry marketing practices. In the petition, Eaton alleges that "the drug has been misbranded and has contained false and misleading labeling and advertising since its entry into the market." Additionally, he says McNeil submitted false postmarketing experience reports to FDA for years, concealing liver damage reports that were in its possession.

A McNeil spokesperson said the company is withholding comment until after FDA has published the petition for public comment in the Federal Register.

COMPANY NAMES:
McNeil Consumer Products Co
FDA
GEOGRAPHIC NAMES: US

DESCRIPTORS: FDA **approval** ; Pharmaceuticals; False information
CLASSIFICATION CODES: 9000 (CN=Short Article); 9190 (CN=United States); 8641 (CN=Pharmaceuticals industry); 4310 (CN=Regulation)

TEXT: Back in the days when FDA only took two months to **approve** a new drug and **approval** was **automatic** if the agency delayed past the statutory **deadline** (pre-1962), McNeil Pharmaceutical conducted a prolonged and successful effort to hide liver damage data...

DESCRIPTORS: FDA **approval** ;

11/9,K/2 (Item 1 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

04199688 Supplier Number: 46141265 (THIS IS THE FULLTEXT)
KASSEBAUM, BLILEY SCHEDULE FEBRUARY FDA REFORM HEARINGS
Food Chemical News, v37, n51, pN/A
Feb 12, 1996
ISSN: 0015-6337
Language: English Record Type: Fulltext
Document Type: Newsletter; Trade
Word Count: 1837
TEXT:
Sen. Nancy Kassebaum (R-Kan.) and Rep. Tom Bliley (R-Va.) have scheduled hearings on overall reform of the Food and Drug Administration in late February, staffers for the Senate Labor and Human Resources Committee and the House Commerce Committee told a Feb. 7 Progress & Freedom Foundation meeting.

Kassebaum's hearings on her bill (S 1477) are scheduled for Feb. 21 and 22, with a hopeful eye toward a markup around March 15, committee staffer Jane Williams said (See FOOD CHEMICAL NEWS, Feb. 5, Page 28). Labor and Human Resources Committee Chairman Kassebaum sees S 1477 as a top priority, "something she is completely committed to," Williams noted of the retiring senator. The Senate FDA reform bill "offers the opportunity to fundamentally re-think what we're doing, how we're looking at questions of safety [when drug or device applications or food-additive petitions arrive at the FDA] ... and to have an overall vision of how products are reviewed and developed in this country," she added.

Commerce Committee Chairman Bliley, meanwhile, is expected to introduce his own FDA reform bill shortly and to hold hearings Feb. 27.

FDA alone cannot be blamed for the perceived current problems within the agency, Williams noted, adding that Congress "has not done a good job of holding regularly scheduled oversight hearings" to examine parts of the agency and/or the whole agency.

CVM, NCTR Oversight Hearings Slated

To correct that past mistake, the House Government Reform and Oversight Committee plans oversight hearings for the Center for Veterinary Medicine and the National Center for Toxicological Research, among others, in 1996, Anne Marie Finley, a staffer for committee member Rep. Christopher Shays (R-Conn.), told the group. CVM and NCTR have "never been part of a general oversight hearing," she noted, adding: "It should be interesting."

Shays, the chairman of the Human Resources and Intergovernmental Affairs Subcommittee, recently produced a report, "The FDA Food Additive **Review** Process: Backlog and **Failure** to Observe Statutory **Deadline** ," which was **approved** by the full committee (See FOOD CHEMICAL NEWS, Jan. 8, Page 3). Finley said the report could become part of any related legislation but that has not happened yet. Shays is also interested in pushing for better FDA processes for nutraceuticals, functional foods and macroingredients such as the recently approved olestra, she noted.

However, Finley admitted that "industry has in some cases been complicitous in working with the agency on getting to Yes' when probably [their petition] should been rejected initially." Such petitions drive up the numbers of backlogged food-additive petitions, she added.

Meanwhile, at the Commerce Committee, "we get a lot of complaints about FDA - some are trivial and some are you can't believe this story' situations," staffer John Cohrssen said. The committee anticipates "robust discussions" about third-party review of drugs, biologics and food additives at its just-scheduled Feb. 27 hearing, he noted, adding that he is "very appreciative of FDA reform ideas ... trucks [full of them] pull up every day!"

Cohrssen noted that new Sen. Ron Wyden (D-Ore.), who is filling the seat of former Sen. Robert Packwood (R-Ore.) after a January special election, had introduced HR 1742, an FDA reform bill, in the House. Now that he is in the Senate, he is likely to work with Kassebaum on her bill, but, Cohrssen said jokingly, if he introduces his own bill, it can be called the "Wyden-Wyden bill." Wyden's Senate term lasts through 1998.

Commerce Committee member Christopher Cox (R-Calif.), who also is a member of the Oversight and Investigations Subcommittee (whose chairman, Rep. Joe Barton, has been active in FDA reform), is interested in fundamental change of the FDA, his staffer Tom Deusterberg said. As part of agency reform, he added, Cox wants: the "de-monopolization" of FDA; a speeding up of the regulatory review process (most likely through institutional change); better dissemination of information within the agency and from the agency to industry and other affected parties; international harmonization of regulatory procedures; and a change in the "antagonistic culture" of FDA.

Ted Kennedy Strongly Supports' FDA Reform; Holcombe Has Questions About 3rd Party Review

Sen. Ted Kennedy (D-Mass.) "strongly supports responsible, bipartisan reform" of FDA in this Congress, staffer David Nexon said. Kennedy is a long-time member of the Labor and Human Resources Committee. But, Nexon pointed out, the ideas advanced by critics of the FDA for sweeping reform are out of date and based on FDA problems that were in place "five or 10 years ago."

A "huge effort" at fundamental reform could result in throwing out a "base of expertise" at FDA that would not be beneficial to anyone, Nexon added, noting that Kennedy believes "such legislation will not pass." Kennedy is interested in seeing FDA: eliminate unnecessary regulation; eliminate export burdens for U.S. companies; speed up the approval processes; and move forward in efforts to allow pre-approval of drugs.

Adding to the Democratic side of the issue, Kay Holcombe, staffer for Rep. John Dingell (D-Mich.), said one of the problems about FDA reform is that "we've all been assigning blame and now is the time to stop that and work together." She added: "If Congress wants to reform FDA, we can do it, and we don't have to make excuses or arguments."

A former FDA official, she noted that "changing the fundamental structure of regulation under the Federal Food, Drug, and Cosmetic Act is a very difficult project." She said she had a few questions to raise about reform ideas propounded by Republicans. For example, while she agreed that third-party review of drug and food additive petitions is a "very good idea," she asked, "Who and where are these third parties? Are there that many academics just lusting to do third-party reviews?"

Also, "How do we know that third-party panels will be faster than FDA?" Holcombe noted, adding: "Our consumers are different from other consumers. We expect everything to be perfect and, if it's not, we're not happy about it." Resolution of potential conflict-of-interest problems raises another question, as does the projected situation of FDA having responsibility for compliance and enforcement efforts over products that FDA did not initially review (ones that are approved by a third-party panel), she said, wondering if FDA personnel might be reluctant to do so.

Henry Miller, co-author of a Progress & Freedom Foundation report released at the meeting - "Advancing Medical Innovation: Health, Safety and the Role of Government in the 21st Century" - told Nexon and Holcombe that there are "many [qualified] people willing to do third-party panels." The University of California at San Francisco recently let go a number of clinical-trial scientists because of a lack of funds, he pointed out, and they would be likely to jump at the chance to serve on a panel. A number of other academic institutions are cutting back these days, he added, and could be a source of panelists as well.

Burr Introduces Bill to Amend FFDCA to Revise Drug Scientific Information Dissemination

Rep. Richard Burr (R-N.C.) on Feb. 1 introduced HR 2932 to amend the FFDCA to revise the requirements of the act relating to the dissemination of scientific information on drugs. Rep. Charles Stenholm (D-Texas), a member of the Agriculture Committee and former chairman of that committee's livestock subcommittee, noted his support for the Burr bill, saying HR 2932 "would allow the holder of an approved new drug application to provide health professionals a reprint of a medical journal article that includes information about the drug that is not in the FDA- approved package insert."

Senate Version of Farm Bill Contains Provisions for Redirecting Funds For Food Safety Research

The Senate version of the farm bill contains a provision stating that the secretary of Agriculture may transfer up to 5% of any amounts made available to a USDA agency responsible for food safety, animal or plant health to a USDA agency reporting to the under secretary of agriculture for research, education and economics "for the purpose of addressing imminent or emerging threats to food safety and animal and plant health." The bill notes that one of the purposes of federally supported agricultural research, extension and education is to improve risk management in the U.S. agriculture industry.

The bill also allows the USDA secretary to "establish and award grants for projects for a multi-year research initiative on human nutrition intervention and health promotion." The projects are supposed to specifically emphasize coordinated longitudinal research assessments of nutritional status and the implementation of unified, innovative intervention strategies that would identify and solve problems of nutritional inadequacy and contribute to the maintenance of health, well-being, performance and productivity of individuals, thereby reducing the need of the individuals to use the U.S. health care system and social programs.

The Agricultural Research Service administrator would administer the grants' funds in order to ensure a coordinated approach to health and nutrition research efforts. The appropriations for the grants would be authorized for fiscal years 1996 through 2002.

A related part of the Senate bill would authorize the secretary of agriculture to ask the National Academy of Sciences to conduct a study of the ARS role and mission. The study is supposed to: evaluate the strength of ARS science and its relevance to national priorities; examine how ARS work relates to the capacity of the U.S. agricultural research, education and extension system overall; and include recommendations, as appropriate. The secretary has 18 months after the NAS study is completed to prepare a report that describes the study and submit the report to the House and Senate Agriculture Committees.

Senate Tea Board Bill Passes; No House Counterpart Is Brewing Yet

The Senate has voted to dump the Board of Tea Examiners, but no similar bill has been introduced in the House, AP reported. The board, created in 1897, consists of one full- time FDA employee and six outside experts. They meet for two days each year in a Brooklyn warehouse to sample teas from all over the world to determine which are of sufficient quality to drink and thereby get onto the U.S. market.

The board costs less than $200,000 to operate annually, but bill cosponsor Sen. Harry Reid (D-Nev.) said it wasn't the cost, it's the fact that "we don't have a coffee board or a candy board. We do not need this tea board." An earlier attempt to get rid of the board occurred when such a measure was added to the 1996 spending bill for the FDA; but in the final bill, the tea board was not eliminated.

Antimicrobial Pesticide Bill Support Urged; Measure May Be Incorporated into HR 1627

Sens. Rod Grams (R-Minn.) and Howell Heflin (D-Ala.) have written senators urging them to support the Antimicrobial Pesticide Registration Reform Act of 1995 (S 1491) (See FOOD CHEMICAL NEWS, Feb. 5, Page 28).

Chemical Specialties Manufacturers Association President Ralph Engel told our sister publication, PESTICIDE & TOXIC CHEMICAL NEWS, that industry intends to incorporate the bill into a Senate food safety bill as sooon as one is introduced and also plans to incorporate it into HR 1627, the Food Quality Protection Act.

PUBLISHER NAME: Food Chemical News, Inc.
EVENT NAMES: *970 (Government domestic functions)
GEOGRAPHIC NAMES: *1USA (United States)
PRODUCT NAMES: *9124230 (Food & Drug Administration)
INDUSTRY NAMES: BUSN (Any type of business); CHEM (Chemicals, Plastics and Rubber); FOOD (Food, Beverages and Nutrition)
NAICS CODES: 92614 (Regulation of Agricultural Marketing and Commodities)

... the Human Resources and Intergovernmental Affairs Subcommittee,

recently produced a report, "The FDA Food Additive **Review** Process: Backlog and **Failure** to Observe Statutory **Deadline** ," which was **approved** by the full committee (See FOOD CHEMICAL NEWS, Jan. 8, Page 3). Finley said the...

28/9,K/33 (Item 3 from file: 636)
DIALOG(R)File 636:Gale Group Newsletter DB(TM)

03825908 Supplier Number: 48305791 (THIS IS THE FULLTEXT)
TELEPHONY
Communications Daily, v18, n34, pN/A
Feb 20, 1998
ISSN: 0277-0679
Language: English Record Type: Fulltext
Document Type: Newsletter; Trade
Word Count: 1987
TEXT:
FCC at agenda meeting Thurs. proposed streamlining wireless application rules to clear way for automated Universal Licensing System, which is scheduled to begin in Sept. Wireless Bureau Chief Daniel Phythyon said new system will consolidate 41 forms into 5 and replace 11 licensing systems. ------

FCC got demonstration of new "speech-to-speech" service at agenda meeting Thurs. Service, variation of Telecom Relay Service (TRS), helps people with speech disabilities make telephone calls. Person with disability calls special phone number to reach translator trained to understand difficult speech patterns. Translator dials other party and stays on line to repeat disabled person's words. Service is available only in Md., Cal., Wis., and soon Ga. ------

High-bid total rose 30% to $278.1 million Thurs. in 2nd round of FCC's local multipoint distribution service (LMDS) auction, up from $192.6 million day earlier. Figures reflect net revenue. Top market remained L.A., where NextBand Communications, venture of Nextel Communications and Craig McCaw's NextLink, bid $36 million, nearly doubling WNP Communications $18 million bid in first round. ------

SBC rewarded Chmn. Edward Whitacre with nearly $1 million in extra pay and bonus last year, reflecting "excellent" personal performance during Pacific Telesis merger and role in merger with Southern New England Telephone (SNET), latest filing at SEC showed. Whitacre's base pay jumped to $975,000 from $900,000, bonus to $3.3 million from $2.5 million, other compensation to $407,455 from $259,255. BellSouth Chmn. Duane Ackerman didn't fare as well as dirs. increased pay to $825,000 from $610,000 in 1996, year before he took over as CEO, but skipped bonus. "Due to the fact that Mr. Ackerman was newly promoted to his position, Mr. Ackerman's 1997 salary was not set at the market-competitive level," proxy said. "However, assuming satisfactory performance, the [Compensation] Committee intends to increase Mr. Ackerman's salary to a market-competitive level over the next few years." SBC and BellSouth are first to file proxies ahead of shareholder meetings in late April -- SBC April 24 in San Antonio, BS April 27 in Atlanta. Other big telecom carriers will follow shortly. SBC said Whitacre "was instrumental" in RHC's being named "world's most admired telecommunications company" in Fortune magazine poll of industry executives, filing showed. In addition to pay boost and bonus increase, board at end of last year also gave Whitacre 50,000 "phantom" stock units that can be converted to one share of stock each, plus 100,000 shares of restricted stock worth $11 million. Ackerman received 206,000 BS shares at $44.38 each, but will gain only if they sell at higher price when options mature in 2007, company said. ------

Rural Cellular Corp. agreed to buy systems in Mass., N.H., N.Y. and Vt. from Atlantic Cellular for $265 million in cash, increasing coverage to 2.85 million potential customers from 1.75 million, subscriber base to 179,000 from 111,000. Rural earlier bought cellular licenses in Me. CEO Richard Ekstrand said Atlantic had invested $40 million in New England network, giving it "clear competitive advantage" in coverage. Deal includes 6 licenses: Rural service area (RSA) 1, RSA 2 and Burlington metro service area, all Vt.,; Western N.H. RSA 1; Northeast N.Y. RSA 2; Northeast Mass. RSA 1. ------

Winstar Communications obtained 17 additional 38-GHz licenses for 33 channels in 13 major cities, giving it 1,000 MHz in 3 cities, 900 MHz in 6 others, company said. FCC **approved** 11 applications pending since 1994 and

company acquired 6 others from unidentified company, subject to Commission **approval** . ------

ADC Communications opened $26-million factory in Shakopee, Minn., to make equipment for wireless industry and announced plans to expand employment by about 15%, to 700. Govt. officials joined executives in opening plant, which was built with $250,000 grant from state. ------

U S West Chmn. Richard McCormick urged business leaders to diversify work forces and vendor lists or risk losing business as population grows more diverse through next century. "Building a diverse work force is not a program," he said at Equal Employment Advisory Council meeting in D.C. "It's not something you do today and then move on to something else tomorrow. It's a process you start now and continue forever." McCormick said forecasts show U.S. population by 2050 will be 25% Hispanic, 14% African American and 8% Asian-American, and 80% of small businesses will be owned by women. To sell to those markets, companies must "understand and reflect them," he said. ------

HitCom acquired Channel Telecom prepaid calling card provider in Canada for 3.8 million shares of stock, worth $4.6 million, and $175,000 cash, expanding its sales by 30% based on HitCom's last-year revenue. Executives said deal advanced HitCom's 3-year plan for expansion. ------

TeleServices International said it bought Compact Connection, Santa Ana, Cal., for $15 million, adding 1.5 million customers to its inbound teleservices business. Compact had about $14 million in revenues and $1.4 million in profit last year. ------

Level 3 Communications picked 46-acre site northwest of Denver for hq and almost 2,000 employees, some transferred from Omaha and Chicago, many hired in Colo. CEO James Crowe said company sought site near international airport with infrastructure to support growth. ------

Bell Atlantic activated 4 asynchronous transfer mode (ATM) switches on Access N.J. (ANJ) project, meeting goal of deploying broadband technology in state as part of 17-year network modernization project. Schools and libraries will have access to network at discount, company said. ------

Alltel converted 160,000 GTE Wireless customers in Ia. and Ill. to new version of customer care and billing software system, and upgraded features used in GTE's PCS markets in Cincinnati, Seattle, Spokane. ------

Powertel, Ericsson and Sendit plan this year to introduce wireless Internet service using Sendit software and Powertel PCS network. Ericsson is providing handsets to handle e-mail and other data features. ------

Qualcomm and AirTouch agreed to test of CDMA data technology using devices and infrastructure provided by Lucent and 3Com. Test will begin by end of March, will continue through year. ------

GSM accounts for 31% of worldwide wireless market and could reach 100 million units by year- end, 2 years ahead of earlier forecasts, GSM MoU Assn. reported. Assn. Chmn. Adriana Nugter said 66 million customers signed up for GSM last year, double level of 1996. "Our next major landmark target is to achieve 50% of the global cellular market -- 256 million customers -- by 2001," she said at meeting in Cannes, France. ------

AT&T prepared network disaster drill for Salt Lake City Sun., near Hogle Zoo, that will simulate replacing central switching office used to route long distance calls. Drill is among 4 conducted annually, company said. ------

Motorola introduced small and light-weight base stations and other equipment to provide in-building coverage and capacity for GSM networks. ------

BellSouth and EDS entered 5-year agreement to develop managed network services using Internet protocol-based networks, terms not announced. ------

Frontier Communications unveiled new logo with stylized ring that represents synchronous optical network added to existing lowercase corporate symbol. Frontier said it plans radio and newspaper ads next week to promote logo. ------

World Wireless Communications said it received order from Len Gordon Co. to design and produce wireless controls to operate portable spas and in-ground pools. Order includes handset remote control that's used to adjust settings using wireless technology. ------

Infiniti added cellular phone docking station in some models of its

luxury auto, giving drivers ability to place and answer calls without using hands. Wireless remote page mounted on steering wheel also gives driver 6 functions in using phone linked to car's audio system. ------

Bell Atlantic (BA) and Chase Manhattan Bank introduced credit card without annual fee that allows customers to earn credits on phone bills by charging purchases to card. Chase plans to issue 70,000 cards to holders of former Nynex/Chase cards. In Aug., Chase bought Bell Atlantic Visa portfolio from First Omni Bank. Cards have 6.9% interest rate for 9 months, with adjustable rates reflecting balance and for cash advances after initial period. ------

N.Y. PSC said Wed. it will pursue penalties against AT&T if it receives more complaints against company for slamming. PSC Chmn. John O'Mara said company submitted plan for reducing problem last June, but complaints declined only slightly and have started to rise again in last 4 months. He said PSC has received 371 complaints against AT&T since June and it's "time to draw the line." PSC spokesman said action is part of general crackdown against slammers. He said most major long distance companies, including MCI, Sprint and LCI, also have filed antislamming plans. Under new antislamming law that went into effect Jan. 20, PSC can fine AT&T $1,000 per violation. AT&T Vp Michael Morrissey said company "shares the same concerns" as Commission and is "committed" to preventing slamming. ------

Southwestern Bell unit of SBC Communications asked Kan. Corp. Commission to endorse planned spring Sec. 271 petition to FCC for interLATA long distance authority in Kan. Telco said it believes it has done everything required under Telecom Act to open its Kan. local markets to competition. Telco's Feb. 18 petition in Kan. follows petition last week to Okla. Corp. Commission for 2nd Sec. 271 **review** there. First was rejected by FCC last year, action that led to SBC's successful lawsuit against Sec. 271 process as unconstitutional bill of attainder, which has been stayed pending federal appellate court **review** . ------

Ind. Senate is scheduled to take final vote Feb. 24 on bill (HB-1376) to prohibit cities from unreasonably denying or delaying public utility access to public rights-of-way (ROW). Measure also would prohibit imposition of non-cost-based local fees for managing ROW. It passed House 85-13 Feb. 3 and was **approved** by Senate Commerce & Consumer Affairs Committee Feb. 17. Any floor amendments to bill must be adopted by Feb. 23. Ameritech has been lobbying in support of bill, saying it would prohibit imposition of local ROW taxes on telecom companies such as one voted in Jan. by Gary, Ind. Ameritech has challenged tax in state's Lake County Superior Court as unlawful action that singles out telecom companies for unfair taxation and represents infringement on state utility commission's jurisdiction. However, lobbyists for municipalities say they should have same rights as private property owners to seek fair market value for use of property, or at least amount sufficient to cover costs, including depreciation and degradation of ROW. ------

Bill in Alaska (HB-416) would require state PUC to promote local competition in service areas of any telco larger than 1,500 lines, using all methods allowed by Telecom Act. Bill, assigned to House State Affairs & Finance Committee Feb. 18, would require PUC by Dec. 31 to reform universal service and access charge rules in manner consistent with promoting local competition and adopt whatever other regulations are necessary to foster speedy development of competition. PUC also would be required to **approve** competitive certification applications within 90 days of filing, and inaction by **deadline** would mean **automatic approval** . Competitive provider General Communications Inc. (GCI) of Anchorage has been lobbying for bill, saying it would benefit consumers by speeding development of competition that would lower prices, improve service, enhance economic development. ------

Mo. PSC will hold 5 hearings March 12-25 to collect comments on Internet issues. Hearings are part of PSC study of changes needed to facilitate public access to Internet. PSC asked each intervenor and service provider in proceeding to file position paper by March 3 outlining Internet access services and rates now available and offering specific suggestions for rule changes to improve their availability and affordability. PSC also **approved** negotiated wireless interconnection agreement between GTE and

Atlas Mobilfone. ------

N.Y. PSC commended 32 independent telcos and 3 Bell Atlantic (BA) operating units Feb. 18 for outstanding service quality. BA units cover S. Manhattan, Midtown Manhattan and Queens in N.Y.C. Commendations were for superior efforts in clearing customer trouble reports and having ultra-low complaint rates to PSC.

PUBLISHER NAME: Warren Publishing, Inc.

INDUSTRY NAMES: BUSN (Any type of business); TELC (Telecommunications)

... it 1,000 MHz in 3 cities, 900 MHz in 6 others, company said. FCC **approved** 11 applications pending since 1994 and company acquired 6 others from unidentified company, subject to Commission **approval** . ------

ADC Communications opened $26-million factory in Shakopee, Minn., to make equipment for wireless industry...petition in Kan. follows petition last week to Okla. Corp. Commission for 2nd Sec. 271 **review** there. First was rejected by FCC last year, action that led to SBC's successful...

...271 process as unconstitutional bill of attainder, which has been stayed pending federal appellate court **review** . ------

Ind. Senate is scheduled to take final vote Feb. 24 on bill (HB-1376) to...

...based local fees for managing ROW. It passed House 85-13 Feb. 3 and was **approved** by Senate Commerce & Consumer Affairs Committee Feb. 17. Any floor amendments to bill must be...

...regulations are necessary to foster speedy development of competition. PUC also would be required to **approve** competitive certification applications within 90 days of filing, and inaction by **deadline** would mean **automatic** **approval** . Competitive provider General Communications Inc. (GCI) of Anchorage has been lobbying for bill, saying it...

...and offering specific suggestions for rule changes to improve their availability and affordability. PSC also **approved** negotiated wireless interconnection agreement between GTE and Atlas Mobilfone. ------

N.Y. PSC commended 32 independent...

?

6/6,K/1 (Item 1 from file: 15)

02103781 65967989
USE FORMAT 9 FOR FULL TEXT

Year-end wrap-up
Nov/Dec 2000 LENGTH: 2 Pages
WORD COUNT: 1611

...TEXT: cogency of TEI's arguments, but also because it was prepared under an extremely short **deadline** . The document was drafted, **reviewed** , and **approved** by the Institute's Executive Committee, all within 11 days of the release of the...

6/6,K/2 (Item 2 from file: 15)

01833677 04-84668
USE FORMAT 9 FOR FULL TEXT

Long-term goal
May 1999 LENGTH: 2 Pages
WORD COUNT: 458

...TEXT: SB's influenza product in February. The company is hopeful that the extension of the **review** beyond the original **deadline** of April is a sign that Relenza-already **approved** in Australia and Sweden-will be available in the United States in time for the...

6/6,K/3 (Item 3 from file: 15)

01833676 04-84667
USE FORMAT 9 FOR FULL TEXT

Penalty & profit
May 1999 LENGTH: 1 Pages
WORD COUNT: 2036

...TEXT: SB's influenza product in February. The company is hopeful that the extension of the **review** beyond the original **deadline** of April is a sign that Relenza-already **approved** in Australia and Sweden-will be available in the United States in time for the...

6/6,K/4 (Item 4 from file: 15)

01469852 01-20840
USE FORMAT 9 FOR FULL TEXT

Cost/schedule management of government construction subcontracts
Jul 1997 LENGTH: 8 Pages
WORD COUNT: 6351

...TEXT: subcontractor submits the construction schedule and schedule of values to the project controls engineer for **approval** (unless some other **deadline** has been specified in the subcontract).

Review of the Schedule and Schedule of Values

The review of the schedule and schedule of...

6/6,K/5 (Item 5 from file: 15)

01145980 97-95374
USE FORMAT 9 FOR FULL TEXT
Inside FDA: Looking for calm in the eye of the storm
Dec 1995 LENGTH: 9 Pages
WORD COUNT: 6845

...TEXT: issues. Using outside reviewers, accepting summary data in place of case report forms, honoring foreign **approvals** , and establishing tacit approvals after a decision **deadline** --all have generated discussion in Congress as ways of making **reviews** more industry-friendly.

As for the use of outside reviewers, Woodcock says she has no...

6/6,K/6 (Item 6 from file: 15)

01032500 96-81893
USE FORMAT 9 FOR FULL TEXT
What's really the matter with FDA
May 1995 LENGTH: 3 Pages
WORD COUNT: 2285

...TEXT: University of Chicago economics professor Sam Peltzman suggests broad structural reform based on an automatic **approval deadline** policy. Hutt likes the idea of a "statutory hammer" that requires FDA to act on...

...automatically approved, similar to the existing policy for INDs. Another proposal is to set a **deadline** of three months for FDA to **review** an application for a drug that the European Medicines Evaluation Agency has already **approved** ; if FDA fails to object before the **deadline** , the product is automatically **approved** .

That kind of radical change is needed, according to some FDA critics, because industry cannot...

6/6,K/7 (Item 7 from file: 15)

00901080 95-50472
USE FORMAT 9 FOR FULL TEXT
Regulation of drugs and devices: An evolution
Summer 1994 LENGTH: 23 Pages
WORD COUNT: 10137

...TEXT: Class III, as well as substantially equivalent postenactment devices. Neither group would be subject to **review** , however, until the FDA announced a **deadline** for the submission of premarket **approval** (PMA) applications. The statute prescribed no timetable for such announcements.(47)

The FDA proceeded slowly...

6/6,K/8 (Item 8 from file: 15)

00626686 92-41788
USE FORMAT 9 FOR FULL TEXT
Oil Facilities Brace for New Spills Rules
Jul 1992 LENGTH: 2 Pages

WORD COUNT: 792

...ABSTRACT: The 2nd rule, requiring oil-handling facilities to develop spill response plans that meet government **approval** , will likely miss that **deadline** . The delay will cause problems for oil handling and storage companies that must meet a...
...TEXT: a second rule, requiring oil handling facilities to develop spill response plans that meet government **approval** , will likely miss that **deadline** , the Coast Guard recently acknowledged.

The delay will put the squeeze on oil handling and...

...to develop a response plan.

"The delay may result in a lot of redoing and **reviewing** of plans that were submitted to meet the February **deadline** ," Prokop says.

The Coast Guard puts the first-year compliance costs for facilities at between...

6/6,K/9 (Item 1 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

07558939 Supplier Number: 63022589 (USE FORMAT 7 FOR FULLTEXT)
OXLEY TACKS FCC LOBBYING AMENDMENT ON MERGER REFORM BILL.
June 28, 2000
Word Count: 893

... 3) Pickering, that FCC must make clear what is required in application, and any merger **review** completed by end of **deadline** will be treated as **approved** .
In opening statement Pickering read from letter to Tauzin and Markey from Senate Antitrust Subcommittee...

6/6,K/10 (Item 2 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

07291906 Supplier Number: 61796296 (USE FORMAT 7 FOR FULLTEXT)
EADS DECISION DELAYED AS EU MERGER TASK FORCE STUDIES REGULATORS' QUERIES.(Government Activity)(International Pages)(Brief Article)
April 26, 2000
Word Count: 488

(USE FORMAT 7 FOR FULLTEXT)
TEXT:
...opted to extend the routine first-phase inquiry by two weeks - creating a new competition **review deadline** of May 11. The European Commission's merger control authorities have extended by two weeks the **deadline** for finishing their first-stage **review** of the EADS merger, from their earlier scheduled date of April 27.Although such an...

...A Commission official recently said the move could be seen as "a good sign" that **approval** will come swiftly. The EU executive extended the **deadline** following submissions from EADS officials, which were offered in response to queries raised by the...

6/6,K/11 (Item 3 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

07174405 Supplier Number: 60580919 (USE FORMAT 7 FOR FULLTEXT)
Visudyne 'approvable'.

March 15, 2000
Word Count: 448

... all the additional data that it has requested, but it had not completed a thorough **review** of that information by the **deadline** , hence the need for " **approvable** " status for the time being.
Lang would not speculate about when final approval would come...

6/6,K/12 (Item 4 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

07049674 Supplier Number: 58245038 (USE FORMAT 7 FOR FULLTEXT)
Stations back bill to spur dawdling FCC on mergers.
April 14, 1999
Word Count: 391

... Kohl, D-Wis., the lead Democratic member on the panel, would require the FCC to **review** and decide on potential mergers within 180 days. If the **deadline** passes without a decision, the merger would be considered **approved** .
"The reason Senator Kohl and I have introduced this legislation is simple: The FCC is...

6/6,K/13 (Item 5 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

07027317 Supplier Number: 59459488 (USE FORMAT 7 FOR FULLTEXT)
GEMSTAR-TV GUIDE VOTE SET.(the companies' proposed merger)(Company Business and Marketing)
Feb 14, 2000
Word Count: 406

... be completed by March 31, although closing can be extended to Sept. 30 if regulatory **approvals** aren't received in time to meet **deadline** . Justice Dept. is **reviewing** proposed merger, requested additional information in Dec., hasn't signed off on deal.
If Gemstar...

6/6,K/14 (Item 6 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

07020953 Supplier Number: 59362501 (USE FORMAT 7 FOR FULLTEXT)
DATA, INTERNET DRIVE 211% INCOME INCREASE FOR MCI WORLDCOM.(Company Financial Information)
Feb 11, 2000
Word Count: 943

... set for next week, he said. Ebbers said he expects FCC to follow 90-day **review** timeline of merger after companies reach March 20 **deadline** to respond to comments. As for state **approvals** , Ebbers said merger is on Fla. PUC agenda this month, on N.Y. PSC agenda...

6/6,K/15 (Item 7 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

06762282 Supplier Number: 56951208 (USE FORMAT 7 FOR FULLTEXT)
Changes in Endovasc Trading Symbol.
Oct 27, 1999
Word Count: 538

... responding to the mandated new filing rule, there is no assurance that SEC will have **reviewed** and **approved** the filing before the **deadline** . If not, the company will be taken off the OTCBB and will be quoted on...

6/6,K/16 (Item 8 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

06428255 Supplier Number: 54952824 (USE FORMAT 7 FOR FULLTEXT)
Southwest Gas-ONEOK Combination Receives Nevada Regulatory Approval **Two Months Ahead of** Deadline ; **Decision Should Set Tone for Other States'** Reviews .
June 22, 1999
Word Count: 519

Southwest Gas-ONEOK Combination Receives Nevada Regulatory Approval **Two Months Ahead of** Deadline ; **Decision Should Set Tone for Other States'** Reviews .
... Public Utilities Commission."
The PUCN decision was rendered two months ahead of the August 19 **deadline** imposed under Nevada state law. **Approval** by Arizona and California regulators is expected to be obtained in time to allow consummation...

6/6,K/17 (Item 9 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

06331549 Supplier Number: 54606498 (USE FORMAT 7 FOR FULLTEXT)
World news & analysis.(Company Business and Marketing)
May, 1999
Word Count: 2050

... SB's influenza product in February. The company is hopeful that the extension of the **review** beyond the original **deadline** of April is a sign that Relenza-already **approved** in Australia and Sweden-will be available in the United States in time for the...

6/6,K/18 (Item 10 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

05757412 Supplier Number: 50242570 (USE FORMAT 7 FOR FULLTEXT)
FDA "Harms Health By Failing Review Deadlines"
August 17, 1998
Word Count: 769

... of simple medical devices, though still earning a D in that category.
Despite a mandatory **deadline** of 180 days for **reviewing** New Drug Applications, **review** time grew from 596 days to 651 days. The FDA received an F on its...

...given observers tools with which to gauge its performance.
Even if the FDA meets an **approval deadline** , the fact that it has suppressed a drug at all can be devastating, says the...

6/6,K/19 (Item 11 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

05378187 Supplier Number: 48178334 (USE FORMAT 7 FOR FULLTEXT)
TELEPHONY

Dec 15, 1997
Word Count: 535

... of meeting entry requirements, aide said.
For 3rd time, FCC Common Carrier Bureau Fri. extended **deadline** for **reviewing** new "contribution factors" that will be used to determine how much money companies must pay...

...data submitted by Schools & Libraries Corp., Rural Health Care Corp., Universal Service Administrative Co. Original **deadline** was Nov. 28. New extension means factors will be deemed **approved** on Dec. 16 unless FCC takes action to change them.
PageNet customers with toll-free...

6/6,K/20 (Item 12 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

04885051 Supplier Number: 47185497 (USE FORMAT 7 FOR FULLTEXT)
FERC Settles PJM Pricing Problem--For Now
March 5, 1997
Word Count: 351

... pool and single-system holding company open access tariffs before the FERC-imposed March 1 **deadline** . But **approval** for all 11 is only temporary, pending further **review** and subject to refund. A 12th tariff, that for the Colorado Power Pool, will take...
?ds

Set	Items	Description
S1	5628	REVIEW? (10N) (DEADLINE OR (TERMINATING (5N) PERIOD))
S2	7144	APPROV? (10N) (DEADLINE OR (TERMINATING (5N) PERIOD))
S3	171	S1 AND S2
S4	125	RD (unique items)
S5	108	S4 NOT PY>2001
S6	92	S4 NOT PY>2000

?t s6/6,k/21-92

6/6,K/21 (Item 13 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

04231973 Supplier Number: 46194635
Private agencies could speed drug approval
March 2, 1996

ABSTRACT:
...a further two for the FDA to grant approval. The FDA has 180 days to **approve** a drug, however, it routinely misses this **deadline** . Under the bill, companies would be able to employ private companies to **review** clinical trials, if the **deadline** was missed by the FDA. The private company would have the power to approve the...

6/6,K/22 (Item 14 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

04199688 Supplier Number: 46141265 (USE FORMAT 7 FOR FULLTEXT)
KASSEBAUM, BLILEY SCHEDULE FEBRUARY FDA REFORM HEARINGS
Feb 12, 1996
Word Count: 1837

... the Human Resources and Intergovernmental Affairs Subcommittee, recently produced a report, "The FDA Food Additive **Review** Process: Backlog and Failure to Observe Statutory **Deadline** ," which was **approved**

by the full committee (See FOOD CHEMICAL NEWS, Jan. 8, Page 3). Finley said the...

6/6,K/23 (Item 15 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

04190071 Supplier Number: 46124690 (USE FORMAT 7 FOR FULLTEXT)
KASSEBAUM FDA-REFORM BILL HEARINGS EXPECTED TO TAKE TWO DAYS IN LATE FEBRUARY, EARLY MARCH, STAFFER SAYS
Feb 5, 1996
Word Count: 1587

... complex, time-consuming and expensive during the past few decades.
Meanwhile, "The FDA Food Additive **Review** Process: Backlog and Failure to Observe Statutory **Deadline** ," a report **approved** by the House Government Reform and Oversight Committee in late December, has not yet made...

6/6,K/24 (Item 16 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

04096304 Supplier Number: 45969750 (USE FORMAT 7 FOR FULLTEXT)
CDER's Janet Woodcock: Looking for Calm in the Eye of the Storm, Part 2
Dec, 1995
Word Count: 1224

... issues. Using outside reviewers, accepting summary data in place of case report forms, honoring foreign **approvals** , and establishing tacit approvals after a decision **deadline** --all have generated discussion in Congress as ways of making **reviews** more industry-friendly.
As for the use of outside reviewers, Woodcock says she has no...

6/6,K/25 (Item 17 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

04075215 Supplier Number: 45933980 (USE FORMAT 7 FOR FULLTEXT)
EC approves Dow purchase of petrochemical complex
Nov 13, 1995
Word Count: 407

... the conditions and go through with the deal.
Ashanin said Dow has not put a **deadline** on its **review** of the European Commission's **approval** and conditions, but said she expects the review period "to be measured in weeks."

6/6,K/26 (Item 18 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

03938721 Supplier Number: 45697170 (USE FORMAT 7 FOR FULLTEXT)
Legent-CA Deal Delayed; Justice and CA discussing market issues
July 31, 1995
Word Count: 278

(USE FORMAT 7 FOR FULLTEXT)
TEXT:
...Legent Corp., an accounting software developer. The Justice Department has asked CA to extend its **deadline** for **approval** of the acquisition to July 21 to **review** the deal more thoroughly.

6/6,K/27 (Item 19 from file: 16)

03844141 Supplier Number: 45503648 (USE FORMAT 7 FOR FULLTEXT)
What's Really the Matter with FDA
May, 1995
Word Count: 2289

... University of Chicago economics professor Sam Peltzman suggests broad structural reform based on an automatic **approval deadline** policy. Hutt likes the idea of a 'statutory hammer' that requires FDA to act on...

...automatically approved, similar to the existing policy for INDs. Another proposal is to set a **deadline** of three months for FDA to **review** an application for a drug that the European Medicines Evaluation Agency has already **approved** ; if FDA fails to object before the **deadline** , the product is automatically **approved** .
That kind of radical change is needed, according to some FDA critics, because industry cannot...

6/6,K/28 (Item 20 from file: 16)

03775815 Supplier Number: 45369159
Administration streamlining electro-optics export licensing process
March, 1995

ABSTRACT:
...Act (EAA), are expected to change this. Strict deadlines will be enforced for interagency license **review** . If an agency holds a license application beyond the **deadline** , its **approval** will be considered implicit. The new process will be put into effect in 1995 and...

6/6,K/29 (Item 21 from file: 16)

02708755 Supplier Number: 43619801 (USE FORMAT 7 FOR FULLTEXT)
DEQ Grants Itself Extension
Feb, 1993
Word Count: 468

(USE FORMAT 7 FOR FULLTEXT)
TEXT:
Amendments to the Land Ban Exemption Petition Regulations will grant DEQ an extension on its **deadline** for **approving** seven exemption petitions. The rule, which was published as final on Feb. 20, 1993, changes the language contained in LAC 33:V.2242.W which limited the time for departmental **review** to a one-year variance beyond the statutory **deadline** of June 1, 1992. DEQ will now have until June 1, 1995. The department claimed...

6/6,K/30 (Item 22 from file: 16)

01979166 Supplier Number: 42534071 (USE FORMAT 7 FOR FULLTEXT)
FDA overhauls drug approval process
Nov 20, 1991
Word Count: 560

... begin next May with four NDAs, followed by four to eight more in September.
External **reviewers** will bid on NDAs and have a 180-day **deadline**

for completing their **reviews** ; FDA will retain final **approval** authority. FDA will also develop guidelines to prevent the appearance of conflicts of interest in...

6/6,K/31 (Item 23 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

01937038 Supplier Number: 42471580 (USE FORMAT 7 FOR FULLTEXT)
Bids for geographic reclassification top 1,300 for fiscal 1993
Oct 28, 1991
Word Count: 339

... that were reclassified for fiscal 1992, said Arthur Owens, chairman of the Medicare Geographic Classification **Review** Board. Reclassifications must be renewed each year, he said.
The **deadline** for applications for 1993 reclassifications was Oct. 1. Last week, Mr. Owens said 1,328...

...new payment rates to cushion the impact on other hospitals. The AHA also wanted to **review** the **approval** criteria and delay the **deadline** for 1993 applications.
That caused a backlash among other hospitals, especially rural facilities that were...

6/6,K/32 (Item 24 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

01875521 Supplier Number: 42380416 (USE FORMAT 7 FOR FULLTEXT)
W.Va. hospitals oppose AHA reclassification stand
Sept 23, 1991
Word Count: 288

... 50% the Medicare gains awarded to reclassified hospitals for fiscal 1992, delay the 1993 application **deadline** and **review** the **approval** criteria.
The Charleston, W.Va.-based group joined the Idaho, Montana and North Carolina state...

6/6,K/33 (Item 25 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

01855575 Supplier Number: 42350861 (USE FORMAT 7 FOR FULLTEXT)
State associations lash out at AHA's bid to limit impact of hospital reclassifications
Sept 9, 1991
Word Count: 1063

... facilities (MH, Aug. 5, p. 9). In addition, the association wants HCFA to delay the **deadline** for fiscal 1993 applications and **review** criteria for future **approvals** .
AHA officials said they wanted to cushion the financial impact of the reclassification. Because the...

6/6,K/34 (Item 26 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

01717631 Supplier Number: 42144001 (USE FORMAT 7 FOR FULLTEXT)
New round of truck rate hikes set to get under way this week
June 10, 1991
Word Count: 385

... 45 days before the rate hikes take effect. This means that June 14 is the **deadline** for submitting the evidence to the ICC for **review** and **approval** .
Members of the Central States Motor Freight Bureau voted June 3 to seek ICC approval...

6/6,K/35 (Item 27 from file: 16)
DIALOG(R)File 16:(c) 2003 The Gale Group. All rts. reserv.

01030686 Supplier Number: 41132157 (USE FORMAT 7 FOR FULLTEXT)
ARISTECH CHEMICAL CORP. ANNOUNCES EXTENSION OF PROPOSAL DEADLINE
Jan 24, 1990
Word Count: 351

... from potential interested parties and has set
5 p.m. on Jan. 29 as the **deadline** for the receipt of written bids.
The special committee will review all proposals received by that
deadline . Following such revi iew, the special committee may **approve**
any of the proposals and recommend that such proposal be approved by the board of...

6/6,K/36 (Item 1 from file: 148)
DIALOG(R)File 148:(c)2003 The Gale Group. All rts. reserv.

12648604 SUPPLIER NUMBER: 65766336 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Philadelphia Mayor Takes More Time for Stadium Plan.
Oct 5, 2000
WORD COUNT: 274 LINE COUNT: 00024

... by today to give the council time to crunch the numbers before the Nov. 30 **deadline** set for final **approval** . Negotiations had halted earlier in the summer while Street concentrated on the Philadelphia School District...

...in the towel on this issue and remains committed to bringing a proposal before the **deadline** . The City Council does still have time to **review** a plan before the **deadline** , but will have to vote to set aside the $30 million to pay for the...

6/6,K/37 (Item 2 from file: 148)
DIALOG(R)File 148:(c)2003 The Gale Group. All rts. reserv.

10271710 SUPPLIER NUMBER: 20820789 (USE FORMAT 7 OR 9 FOR FULL TEXT)
MCI and WorldCom are seeking single buyer for MCI's Internet assets.
June 18, 1998
WORD COUNT: 389 LINE COUNT: 00033

... before Fri. meeting of 15 antitrust authorities from European Union nations in Brussels.
They will **review** merger and make recommendation for July 15 **deadline** for Commission **approval** or rejection of deal.
"We now feel quite confident we're at a point where...

6/6,K/38 (Item 3 from file: 148)
DIALOG(R)File 148:(c)2003 The Gale Group. All rts. reserv.

08963573 SUPPLIER NUMBER: 18614987 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Generic manufacturers lose merger, gain victories.(Generic Pharmaceutical

Industry Association, National Association of Pharmaceutical Manufacturers)(Washington Perspective)(Column)
August 19, 1996
WORD COUNT: 495 LINE COUNT: 00045

... Senate conferees directed the FDA to earmark sufficient resources to meet the statutory 180-day **deadline** for **reviewing** generic drug **approvals** .
At the same time, generic industry representatives scored a separate victory by blocking a controversial...

6/6,K/39 (Item 4 from file: 148)
DIALOG(R)File 148:(c)2003 The Gale Group. All rts. reserv.

08134691 SUPPLIER NUMBER: 17409209 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Far West bond-watch.
Sep 15, 1995
WORD COUNT: 1565 LINE COUNT: 00128

... have corrected most record-keeping and accounting errors identified by a recent state auditor's **review** of the town's finances ahead of their Sept. 25 **deadline** , according to Councilman Phil Hinds.
The Wyoming Audit Department **approved** Evansville's internal audits for fiscal 1991 through 1994 last month, but also pointed out...

6/6,K/40 (Item 5 from file: 148)
DIALOG(R)File 148:(c)2003 The Gale Group. All rts. reserv.

07187629 SUPPLIER NUMBER: 15154760 (USE FORMAT 7 OR 9 FOR FULL TEXT)
IRS final nondiscrimination rules issued. (Internal Revenue Service)
Jan, 1994
WORD COUNT: 387 LINE COUNT: 00030

... satisfies the minimum coverage requirements based on the average benefit test may choose no IRS **review** of its compliance with this test.
The filing **deadline** for obtaining an IRS **approval** letter for a plan maintained by a for-profit entity is the last day of...

6/6,K/41 (Item 6 from file: 148)
DIALOG(R)File 148:(c)2003 The Gale Group. All rts. reserv.

06198934 SUPPLIER NUMBER: 13600441 (USE FORMAT 7 OR 9 FOR FULL TEXT)
FCC approved . **(extension of comment** deadline **on HDTV rules)**
Oct 26, 1992
WORD COUNT: 154 LINE COUNT: 00012

FCC approved . **(extension of comment** deadline **on HDTV rules)**

TEXT:
FCC **approved** 2-week extension of comment **deadline** in HDTV rulemaking (TVD Aug 14 p6). In order released last week, FCC said extension ...

...in 1996, simulcast and conversion deadlines in 1999 and again in 2002, and conduct final **review** of **deadline** for conversion to HDTV in 2008. In other details in order, FCC: (1) Directed HDTV...

6/6,K/42 (Item 7 from file: 148)
DIALOG(R)File 148:(c)2003 The Gale Group. All rts. reserv.

06162332 SUPPLIER NUMBER: 12798583 (USE FORMAT 7 OR 9 FOR FULL TEXT)
FCC approved **2-week extension of comment** deadline . **(Federal Communications Commission, high-definition television rulemaking)**
Oct 21, 1992
WORD COUNT: 158 LINE COUNT: 00012

FCC approved **2-week extension of comment** deadline . **(Federal Communications Commission, high-definition television rulemaking)**

TEXT:
FCC **approved** 2-week extension of comment **deadline** in HDTV rulemaking (CD Aug 17 p6). In. order released Tues., FCC said extension will...

...16, replies Dec. 16. FCC also released text of order itself, indicating that it will **review** application and construction deadlines in 1993, construction **deadline** again in 1996, simulcast and conversion deadlines in 1999 and again in 2002, and do final **review** of **deadline** for conversion to HDTV in 2008. Other details in order: (1) FCC directs HDTV advisory...

6/6,K/43 (Item 8 from file: 148)
DIALOG(R)File 148:(c)2003 The Gale Group. All rts. reserv.

05925902 SUPPLIER NUMBER: 12565550 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Housing finance: major developments in 1991. (Consumer Financial Services)
May, 1992
WORD COUNT: 7873 LINE COUNT: 00638

... common Interim Rule, portions of USPAP concerning its overall introduction, real property appraisals, reporting and **review** appraisals.(112)
APPRAISER **DEADLINE** EXTENDED
Title XI of FIRREA provided that all appraisals performed in connection with "federally related...

...not have such agencies in place by July 1, 1991, the Appraisal Subcommittee, with the **approval** of the FFIEC, extended the July **deadline** to December 31, 1991.(116) Since Title XI originally provided that the Appraisal Subcommittee could...

6/6,K/44 (Item 9 from file: 148)
DIALOG(R)File 148:(c)2003 The Gale Group. All rts. reserv.

05537649 SUPPLIER NUMBER: 11613125 (USE FORMAT 7 OR 9 FOR FULL TEXT)
FDA overhauls drug approval process. (Food and Drug Administration)
Nov 20, 1991
WORD COUNT: 595 LINE COUNT: 00049

... begin next May with four NDAs, followed by four to eight more in September.
External **reviewers** will bid on NDAs and have a 180-day **deadline** for completing their **reviews** ; FDA will retain final **approval** authority. FDA will also develop guidelines to prevent the appearance of conflicts of interest in...

6/6,K/45 (Item 10 from file: 148)
DIALOG(R)File 148:(c)2003 The Gale Group. All rts. reserv.

05144056 SUPPLIER NUMBER: 10632300 (USE FORMAT 7 OR 9 FOR FULL TEXT)
OMB may need explicit reports of system upgrades. (Office of Management and

Budget)
April 15, 1991
WORD COUNT: 541 LINE COUNT: 00043

... considered the leading candidate for the top OMB management job.
Hodsoll also said OMB will **approve** agency CFO reorganization plans by May. OMB has extended its **deadline** for finishing its **review** of the plans because agency officials had been slow to draft changes before OMB issued...

6/6,K/46 (Item 11 from file: 148)

04635105 SUPPLIER NUMBER: 09201291 (USE FORMAT 7 OR 9 FOR FULL TEXT)
FDA on 'tightrope' in approving drugs; deadlines, outside pressures vie for safety, speed concerns. (part 3)
June 22, 1990
WORD COUNT: 1982 LINE COUNT: 00156

... standing advisory committees, composed of outside experts, may be called upon to help make the **approval** decision.
The painstaking process races against a statutory 180-day **deadline** . The **deadline** usually passes long before the drug is **approved** .
In some ways the FDA is like an adolescent who, despite the best intentions, just...clinical investigators, pharmaceutical manufacturers, even FDA officials -- seems to agree upon, it's that the **review** process should be brought within the statutory **deadline** . Moreover, all seem to agree upon the same simple solution -- give the FDA more people...

6/6,K/47 (Item 12 from file: 148)

04087385 SUPPLIER NUMBER: 07696644 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Green Tree Acceptance announces extension of deadline for Midwest Savings Association F.A. agreement.
Sept 25, 1989
WORD COUNT: 208 LINE COUNT: 00017

... that at the request of Midwest Savings Association F.A., Green Tree has extended its **deadline** for **approval** of the negotiated settlement with Midwest for one week, until Oct. 2. In requesting the...

...is actively proceeding. Due to the many demands placed on these officials, Midwest said the **review** could not be completed by the original Sept. 25 **deadline** .
Green Tree purchases, pools, sells and services conditional sales contracts for manufactured homes and recreational...

6/6,K/48 (Item 13 from file: 148)

03833956 SUPPLIER NUMBER: 07239113 (USE FORMAT 7 OR 9 FOR FULL TEXT)
New pesticide law amendments hold hidden problems, Bureau of National Affairs report indicates. (Federal Insecticide, Fungicide and Rodenticide Act)
Jan 10, 1989
WORD COUNT: 433 LINE COUNT: 00036

... Rodenticide Act (FIFRA), many doubts linger about whether EPA will meet the congressionally mandated 1997 **deadline** for **reviewing** the safety of about 530 older pesticide ingredients.

Among major points discussed in the BNA...

...related costs of testing and user fees.
-- EPA is unlikely to meet the 1997 reregistration **deadline** unless Congress **approves** further changes to the pesticide law, including a streamlining of the administrative hearing process that...

6/6,K/49 (Item 14 from file: 148)
DIALOG(R)File 148:(c)2003 The Gale Group. All rts. reserv.

03281915 SUPPLIER NUMBER: 05130272 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Farm Aid credentials advisory. (Farm Aid III benefit concert)
Aug 26, 1987
WORD COUNT: 114 LINE COUNT: 00009

... accepted. Credentialing cost will be $25 per person. All requests for media credentials will be **reviewed** by Farm Aid III, which reserves the right of **approval** . **Deadline** for applications is Monday, Sept. 14, 1987. Information on application procedures is now available from...

6/6,K/50 (Item 1 from file: 160)
DIALOG(R)File 160:(c) 1999 The Gale Group. All rts. reserv.

00577177
A GAO study has concluded that direct food additives are not adequately regulated.
August 27, 1980

The agency has suggested that Congress amend the Food, Drug & Cosmetic Act to eliminate safety **review** exemptions, and should set a **deadline** for **review** and **approval** of all previously exempt additives. FDA should also formalize criteria for assessing additives safety, define...

6/6,K/51 (Item 1 from file: 9)
DIALOG(R)File 9:(c) 2003 Resp. DB Svcs. All rts. reserv.

2541427 Supplier Number: 02541427 (USE FORMAT 7 OR 9 FOR FULLTEXT)
ICO cancels rights offering, proposes new class of stock
August 02, 1999
WORD COUNT: 359

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...million in convertible subordinated debt notes. Their binding interest is conditional, pending normal due diligence **review** and shareholder and governmental **approvals** . The **deadline** for their interest to become formal is Aug. 10.

Analysts say the new share class...

6/6,K/52 (Item 1 from file: 20)
DIALOG(R)File 20:(c) 2003 The Dialog Corp. All rts. reserv.

14074738 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Lawmakers resume budget debate
December 05, 2000
WORD COUNT: 345

(USE FORMAT 7 OR 9 FOR FULLTEXT)

... on next year's 101-trillion won budget, which the government has said must be **approved** before Dec. 9, the **deadline** for the current session of the National Assembly.

This breakthrough is also expected to allow...

... reforms, inter-Korean relations and government structure might make it hard to adhere to the **deadline** .

"It takes up to 15 days to **review** the budget and at least that much time to examine other bills, but since there...

6/6,K/53 (Item 2 from file: 20)

13365124 (USE FORMAT 7 OR 9 FOR FULLTEXT)

Energy Office confirms delaying gas pricing decision by 30 days

October 17, 2000

WORD COUNT: 134

... negotiations between Mol and the government are at an advanced stage, MTI reported.

The initial **deadline** for the **review** expired in early October but the office **approved** a two week delay as it needed further information from the company. The second deadline...

6/6,K/54 (Item 3 from file: 20)

12429392 (USE FORMAT 7 OR 9 FOR FULLTEXT)

Deadline on Philadelphia Stadium Nears, But Agreement Remains at A Distance

August 16, 2000

WORD COUNT: 949

(USE FORMAT 7 OR 9 FOR FULLTEXT)

... ordinance passed by City Council in the spring, the city is facing a Nov. 30 **deadline** to **approve** a stadium plan. If the **deadline** is not met, the city will pay up to $80 million to fix Veterans Stadium...

...forward the plan to City Council by Sept. 8 so Council members have time to **review** it. The mayor has the option of extending his **deadline** until Oct. 5.

The state has agreed to pay $170 million toward the estimated $1...

6/6,K/55 (Item 4 from file: 20)

10818559 (USE FORMAT 7 OR 9 FOR FULLTEXT)

Environmental Department Can Issue Permit to Greene County, N.Y., Power Plant

May 02, 2000

WORD COUNT: 472

(USE FORMAT 7 OR 9 FOR FULLTEXT)

... enable the state Board on Electric Generation Siting and the Environment to wrap up its **review** of the project by its recently extended **deadline** of May 31.

The siting board, which must **approve** or reject the bulk of permits for the project, wanted DEC's water permit in...

6/6,K/56 (Item 5 from file: 20)

09818364 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Latvian MP's approve deadline **extension in probe of prosecutor general**
February 29, 2000
WORD COUNT: 431

(USE FORMAT 7 OR 9 FOR FULLTEXT)
Latvian MP's approve deadline **extension in probe of prosecutor general**

... faction chairman Dzintars Rasnacs told the BNS that Cizevskis has reason to ask for extended **deadline** because he had lots of material to be **reviewed** and additional information to be obtained from the parliamentary investigation commission. People's Party faction...

6/6,K/57 (Item 6 from file: 20)

07744105 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Washington State Department of Veterans Affairs -- Funds Available for Veterans' Memorials
October 14, 1999
WORD COUNT: 262

(USE FORMAT 7 OR 9 FOR FULLTEXT)

... must meet established criteria and be submitted in writing to the department by the submission **deadline** of December 17. Proposals will be **reviewed** and **approved** or rejected by the VAAC during their January, 2000, meeting.
Since the program's inception...

6/6,K/58 (Item 7 from file: 20)

07565445 (USE FORMAT 7 OR 9 FOR FULLTEXT)
DISPUTE ERUPTS BETWEEN SWAZI CHIEFS AND MPS
September 30, 1999
WORD COUNT: 337

(USE FORMAT 7 OR 9 FOR FULLTEXT)

... traditional leaders who resent the encroachment, and are horrified when development sprouts up without their **approval** .
The Constitutional **Review** Commission faces a December **deadline** to sort out governing responsibilities. A commission critic, Joshua Mzizi of the Human Rights Association...

6/6,K/59 (Item 8 from file: 20)

06874793 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Racetrack Operators Propose New Course in Dumfries, Va.
August 23, 1999
WORD COUNT: 835

(USE FORMAT 7 OR 9 FOR FULLTEXT)

... Prince William planners have expressed serious reservations about whether they can meet a Nov. 30 **deadline** for **approving** the racetrack.

In Dumfries, an incorporated town within Prince William, the decision rests with the...

... said he is cautiously optimistic planners in the town -- population 4,300 -- can complete their **review** in time for the Nov. 30 **deadline** . The town has only three people on its planning staff.
"Out staff has been assigned...

6/6,K/60 (Item 9 from file: 20)
DIALOG(R)File 20:(c) 2003 The Dialog Corp. All rts. reserv.

05345204 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Glaxo says sales to 'increase signifitantly' in coming months
May 17, 1999
WORD COUNT: 455

(USE FORMAT 7 OR 9 FOR FULLTEXT)

... knocked back by a U.S. Food & Drug Administration expert panel which decided against recommending **approval** . However, the FDA has since extended its **deadline** for **reviewing** the data on the drug.

6/6,K/61 (Item 10 from file: 20)
DIALOG(R)File 20:(c) 2003 The Dialog Corp. All rts. reserv.

05027702 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Wound Care Examination Scheduled for Oct. 4 in Denver; Certification by Portfolio to End
April 20, 1999
WORD COUNT: 351

... will end on June 30, 1999. All candidates must complete all portfolio requirements by this **deadline** , in order to be considered for final **review** and, if **approved** , board certification.

6/6,K/62 (Item 11 from file: 20)
DIALOG(R)File 20:(c) 2003 The Dialog Corp. All rts. reserv.

04102613 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Allegheny University Hospitals-West Announces Plan for Protecting Four Area Hospitals
January 22, 1999
WORD COUNT: 556

(USE FORMAT 7 OR 9 FOR FULLTEXT)

... proposals will be selected and presented to a court appointed trustee and bankruptcy court for **review** and **approval** .
The original **deadline** for AUH-West board **approval** of the selected proposal was Monday, January 25. However, as part of on-going negotiations ...

6/6,K/63 (Item 12 from file: 20)
DIALOG(R)File 20:(c) 2003 The Dialog Corp. All rts. reserv.

02277930 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Rhode Island Attorney General Extends Inquiry into Hospital Merger
July 22, 1998
WORD COUNT: 826

(USE FORMAT 7 OR 9 FOR FULLTEXT)

...trouble.
Atty. Gen. Jeffrey B. Pine said yesterday he has added 60 days to the **deadline** for his **review** of the takeover of the Care New England hospital system, because he would not have **approved** it by the first **deadline** , July 3.
... requested have been produced," Pine said.
Asked what would have happened had there been no **deadline** extension, Pine said: "Well, we weren't going to **approve** it, put it that way." Pine added that he's not "overly inclined" to grant...

6/6,K/64 (Item 1 from file: 476)
DIALOG(R)File 476:(c) 2003 Financial Times Ltd. All rts. reserv.

0008505344 B0GFFAAACIFT
News: Asia-pacific: Taiwan premier's reappointment irks opposition
Thursday, June 6, 1996
Word Count: 377

...166.2bn to pay for purchases of fighter jets and other equipment.

The budget was **approved** early yesterday after a May 31 **deadline** had been extended. The budget **review** process was spread over two months marked by disputes and backroom bargaining among parties.

6/6,K/65 (Item 1 from file: 624)
DIALOG(R)File 624:(c) 2003 McGraw-Hill Co. Inc. All rts. reserv.

01055033
DOE FINDS LITTLE TO CHEER IN POWER BILL
November 1, 1999
Word Count: 2,670 *Full text available in Formats 5, 7 and 9*

TEXT:
...19-10.
-- A proposal by Rep. Richard Burr, R-N.C., to require FERC to **review** mergers within 180 days. If that **deadline** is not met, the merger would automatically be **approved** . The measure was passed on a 13-12 show of hands.
Amendments raised and withdrawn...

6/6,K/66 (Item 2 from file: 624)
DIALOG(R)File 624:(c) 2003 McGraw-Hill Co. Inc. All rts. reserv.

0634229
MASS. TO CHARGE AN APPLICATION FEE FOR EMISSION CREDITS IN BANKING PLAN
January 13, 1995
Word Count: 585 *Full text available in Formats 5, 7 and 9*

TEXT:
... growth. After paying the application fee, the applicant and DEP will mutually agree upon an **review** schedule. If the agency fails to meet the **deadline** , it forfeits the fee.

However, the 62 emissions credit applications now pending before the DEP
...

... EPA by November 1994 showing how they would reach compliance. But the states missed the **deadline** because of delays in EPA **approval** of air mass modeling methods the states are using to complete the plans, Greene

said...

6/6,K/67 (Item 3 from file: 624)

0572785
FEDERAL COURT GIVES STATES, INDUSTRY VICTORY; EXTENDS NOx PLAN DEADLINES
May 13, 1994
Word Count: 742 *Full text available in Formats 5, 7 and 9*

TEXT:
...NOx reduction plans.

Since the law gives EPA 14 to 18 months after the submittal **deadline** to **approve** or disapprove the SIP and to determine if states qualify for exemptions from the NOx...

... the exemption timing problem,...it would have elected to accord the EPA the full statutory **review** time."

Accordingly, the court held that EPA's revised **deadline** for submitting NOx plans--Nov. 15, 1993--will stand, and that EPA would have 14 to 18 months after that **deadline** , until May 15, 1995, to **review** and **approve** or disapprove the plans--as Congress intended.

6/6,K/68 (Item 4 from file: 624)

0569734
VEW BRINGS LAWSUIT AGAINST EURATOM, SEEKS CLEARER U PACT APPROVAL RULES
April 25, 1994
Word Count: 683 *Full text available in Formats 5, 7 and 9*

TEXT:
... said the VEW suit charges that ESA did not respect a 10-day decision-making **deadline** in its processing of the utility's application for contract **approval** . On the 10th day after receiving the proposed contract for approval, these sources said, ESA...

... all cases, before submitting it as a so-called "non-publishable decision," allowing VEW to **review** it and meet a separate one-month **deadline** for challenge.

The Commission staff is, however, eager to see the decision published eventually, and...

6/6,K/69 (Item 5 from file: 624)

0539279
MASS. SITING BOARD TURNS DOWN REQUEST TO REOPEN ENERGY NEW BEDFORD CASE
December 24, 1993
Word Count: 271 *Full text available in Formats 5, 7 and 9*

TEXT:
... the Massachusetts Supreme Judicial Court ruled that the board used the wrong standards, forcing another **review** .

The **deadline** to appeal Eastern Energy's siting **approval** is Jan. 18, 1994.

6/6,K/70 (Item 6 from file: 624)

0445081
REAL ESTATE APPRAISAL REFORM
November 11, 1992
Word Count: 13,076 *Full text available in Formats 5, 7 and 9*

TEXT:
...XI also makes any decision rendered by the ASC in this regard subject to judicial **review** .34

The Shifting Appraiser **Deadline**

When FIRREA was passed in August 1989, the Act provided that not later than July... and license appraisers in accordance with the requirements of Title XI by the initial statutory **deadline** of July 1, 1991. Accordingly, the ASC, with the **approval** of FFIEC extended the July **deadline** until December 31, 1991.78 Initially this extension was made effective in only 54 of...

6/6,K/71 (Item 7 from file: 624)

0300128
GAO Wants More Assessment Of Aging Aircraft, Addresses Controller Shortages

May 6, 1991
Word Count: 333 *Full text available in Formats 5, 7 and 9*

TEXT:
... twice as much. FAA said that if carriers cannot make required modifications by the 1994 **deadline** , aircraft will either be grounded or FAA will **review** and **approve** alternate means of compliance.

GAO said other provisions needed in FAA's plan are ones...

6/6,K/72 (Item 1 from file: 634)

04539289
BUDGET ANALYSIS LEADS BACK TO UNCERTAINTY
Monday, May 16, 1988
Word Count: 696

... forms last week gave some support to the theory. However, a more comprehensive, statistically valid **review** won't be completed until long after the June 30 **deadline** for **approval** of the fiscal 1989 budget.

There also have been suggestions over the past two weeks...

6/6,K/73 (Item 2 from file: 634)

04066159
U.S. THREATENS COASTAL COMMISSION
Friday, August 21, 1987
Word Count: 868

...and other permit applicants with ''sufficiently specific and predictable

standards'' and guidelines.

(check) Delayed its **review** and **approval** of federal permits beyond the maximum six-month **deadline** .

(check) ''Failed to provide leadership'' in coastal zone management by not providing sufficient opportunity for...

6/6,K/74 (Item 1 from file: 636)

04704247 Supplier Number: 62970576 (USE FORMAT 7 FOR FULLTEXT)
Improving Communication Among Providers Yields Savings, Improved Outcomes.
June 19, 2000
Word Count: 1231

... send ANOC materials (including

summary of benefits) to HCFA regional offices in order to ensure **review** and **approval** before

October 15 **deadline** .

HCFA begins CY 2001 local information campaign.

M+COs required to include information in CY
...

6/6,K/75 (Item 2 from file: 636)

03929259 Supplier Number: 50190336 (USE FORMAT 7 FOR FULLTEXT)
Enforcement
July 1, 1998
Word Count: 3890

... Third party review of medical devices will likely draw criticism over the short 30-day **deadline** FDA has to **approve** or reject a 510(k) rather than the fact it was reviewed by a private...

...IDE Modifications.
$Final Guidance on Third Party Accreditation Procedures.
AThe critics are saying that the **deadline** pressures are driving them [**reviewers**] too hard and, therefore, they are making decisions that if they weren=t under that...of last month. Although Gustafson admitted that CBER is not meeting the required 90-day **review** **deadline** , these particular 510(k)s have had Areal problems.@
AEverything has had an initial review...

6/6,K/76 (Item 3 from file: 636)

03881229 Supplier Number: 48483168 (USE FORMAT 7 FOR FULLTEXT)
FDA APPROVABLE LETTER PUTS CEPHALON ALS DRUG IN LIMBO By Lisa Seachrist Washington Editor
May 14, 1998
Word Count: 996

... Set For Final FDA Ruling
Reed also noted that because the agency met its statutory **deadline**

under Prescription Drug User Fee Act by issuing the approvable letter Tuesday, the agency no longer has a **deadline** to **review** additional efficacy data and to clear Myotrophin for marketing. In essence, Reed said, the agency...

6/6,K/77 (Item 4 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

03828872 Supplier Number: 48315097 (USE FORMAT 7 FOR FULLTEXT)
INTEL: Intel and leading server vendors introduce server management hardware interface
Feb 25, 1998
Word Count: 775

... specifications and Contributors license agreement are available at developer.intel.com/design/servers/ipmi. The **deadline** for **review** , revisions and final **approval** of v1.0 is late Q2 1998.
*M2 COMMUNICATIONS DISCLAIMS ALL LIABILITY FOR INFORMATION PROVIDED...

6/6,K/78 (Item 5 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

03734387 Supplier Number: 48074900 (USE FORMAT 7 FOR FULLTEXT)
Md. FCU Finally Granted Thrift Charter by NCUA
Oct 27, 1997
Word Count: 196

... March 21, and although the Office of Thrift Supervision and Federal Deposit Insurance Corp. had **approved** the conversion by the July 3 **deadline** , the credit union was still waiting for NCUA to finish **reviewing** the second draft of its disclosure statement to its members.
Moltzan said his board had...

6/6,K/79 (Item 6 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

03704084 Supplier Number: 47995989 (USE FORMAT 7 FOR FULLTEXT)
House Panel Okays FDA Reform; PDUFA Trigger Still at Issue
Sept 22, 1997
Word Count: 282

(USE FORMAT 7 FOR FULLTEXT)
TEXT:
...but "it's our understanding there's enough money sitting there" to tide the drug **review** program over beyond the **deadline** , he says. Among other amendments, the panel **approved** language extending to generic drugmakers the same protections against IDA-imposed, mid-trial design changes...

6/6,K/80 (Item 7 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

03150068 Supplier Number: 46448500 (USE FORMAT 7 FOR FULLTEXT)
HCFA Grants Temporary '75-25' Rule Relief For Florida HMOs Facing Shutdown
June 7, 1996
Word Count: 382

... Systems and Jacksonville-based HealthCare USA have escaped possible shutdowns " at least temporarily " as HCFA **reviews** the state's request to extend the **deadline** for meeting federal Medicaid enrollment composition rules, which HCFA **approved** under Florida's waiver granted two years ago.

The "75-25" rule requires that a...

6/6,K/81 (Item 8 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

02878714 Supplier Number: 45842314 (USE FORMAT 7 FOR FULLTEXT)
MASSACHUSETTS' PERMIT-EASE PROPOSAL NOW DRAWING FIRE FROM 'E' GROUPS
Oct 6, 1995
Word Count: 251

... shopping centers and other major projects.
The proposal would allow state officials 120 days to **review** major projects, including holding public hearings. If the **deadline** is not met, two weeks after the state has been warned of the **deadline** , the project would automatically be **approved** .
Other criticism is directed at a provision to allow the state environmental affairs secretary, a...

6/6,K/82 (Item 9 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

02782643 Supplier Number: 45646659 (USE FORMAT 7 FOR FULLTEXT)
MOTOR INDUSTRY: COURT RULING PROMPTS URGENT ACTION ON STATE AID CODE
July 1, 1995
Word Count: 932

... longer valid as it had been extended for an indefinite period. Because there was no **deadline** imposed for **review** and re-adoption when the Code was last **approved** , the Court imposed its own **deadline** - December 31, 1995.
Major implications for SEAT.
For cases like SEAT, this ruling could have...

6/6,K/83 (Item 10 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

02619764 Supplier Number: 45302062 (USE FORMAT 7 FOR FULLTEXT)
510(k)s took 52 more days to clear in FY '94 versus 1993 Backlog blamed, despite 25% ODE staff increase
Feb, 1995
Word Count: 928

... for medical devices than in fiscal 1993, and more than 55% of devices are in **review** beyond the statutory 90-day **deadline** , according to agency data obtained by MDAL.
The data, which for the first time since...

...never asked before." He also said a "fear factor" engulfed ODE. "Reviewers were afraid to **approve** anything."
The device law gives FDA a 90-day **deadline** for **reviewing** 510(k)s, but changes passed by Congress via the Safe Medical Devices Act of...

6/6,K/84 (Item 11 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

02333170 Supplier Number: 44557459 (USE FORMAT 7 FOR FULLTEXT)
THE GEJDENSON BILL: ANSWER TO INDUSTRY'S PRAYERS?
March 31, 1994
Word Count: 526

...	120 days	days to 90 days. Would allow the Commerce Department 9 days to reach initial decisions on submitted license applications. Would give referral agencies 30 days for **review** , with no extension.	30 days. Failure to meet **deadline** would mean automatic **approval** . Would give the executive branch discretion as to how to meet the **deadline** .
	Foreign Availability	Would expand grounds under which an...	Would give the executive

6/6,K/85 (Item 12 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

02254068 Supplier Number: 44312301 (USE FORMAT 7 FOR FULLTEXT)
Intermodalism Is Central To Pena's Transportation Plan
Dec 23, 1993
Word Count: 649

... after consulting with state and local transportation officials, federal agencies and private concerns. Following a **review** , Congress faces a Sept. 30, 1995 **deadline** for **approving** or rejecting the plan.

6/6,K/86 (Item 13 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

02148665 Supplier Number: 44018299 (USE FORMAT 7 FOR FULLTEXT)
FEDERAL FUNDS WOULD HELP NEW HAMPSHIRE'S SUB D TRANSITION
August 5, 1993
Word Count: 687

... of adequacy, Gilbert said, there is still an outside chance that it could be fully **approved** by the Oct. 9 **deadline** . If the EPA **review** uncovers some areas that are deficient and returns the application to the state to make...

6/6,K/87 (Item 14 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

02113113 Supplier Number: 43922422 (USE FORMAT 7 FOR FULLTEXT)
NAM RELEASES LEGISLATIVE PROPOSAL
June 24, 1993
Word Count: 645

... summary of license processing procedures and an indication of whether the license will require multilateral **review** ;
a 5-day **deadline** for the referral of license applications to other agencies;
a 15-day deadline for the referral agencies to submit a recommendation to the Commerce Department;
a 30-day **deadline** for the Commerce Department to deliver a license denial or **approval** to the applicant (an additional 30-day period is allowed for items requiring multilateral review...

6/6,K/88 (Item 15 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

01986691 Supplier Number: 43558690 (USE FORMAT 7 FOR FULLTEXT)
Planners Await Updated National and Area Contingency Plans
Jan, 1993
Word Count: 381

... local contingency plan ... in effect on August 18, 1992, will be utilized for the consistency **review** of response plans submitted to meet the February 18, 1993, **deadline** ." The USCG also stated that the USCG will not require **approved** plans to be rewritten for the sole purpose of being consistent with a revision to...

6/6,K/89 (Item 16 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

01914070 Supplier Number: 43343684 (USE FORMAT 7 FOR FULLTEXT)
NVICs Give Guidance on Response Plan Requirements
Oct, 1992
Word Count: 1768

... LCP or ACP in effect on August 18, 1992, will be utilized for the consistency **review** of response plans submitted to meet the February 18, 1993, **deadline** ." The NVICs also state that the USCG will not require **approved** plans to be rewritten for the sole purpose of being consistent with an ACP or...

6/6,K/90 (Item 17 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

01428697 Supplier Number: 41888333 (USE FORMAT 7 FOR FULLTEXT)
PROLIFERATION CONTROL REGULATIONS APPROACH FINAL FORM
Feb 25, 1991
Word Count: 2721

... proliferation concern from developing chemical and biological weapons capabilities.
Third, the government's February 16 **deadline** for **approval** and publication of the new controls hampered industry's ability to express its concerns about...

...list of countries to which the new proliferation controls would apply.
In spite of the **deadline** , industry and government completed an extensive **review** of the list of proposed controls on chemical and biological equipment. The first draft of...

6/6,K/91 (Item 18 from file: 636)
DIALOG(R)File 636:(c) 2003 The Gale Group. All rts. reserv.

01426282 Supplier Number: 41879395 (USE FORMAT 7 FOR FULLTEXT)
VOC RULES CHANGES PROPOSED
Feb 20, 1991
Word Count: 509

(USE FORMAT 7 FOR FULLTEXT)
TEXT:
...VOCs). The changes, which must be in effect by a 1990 Federal Clean Air Act **deadline** of May 15, 1991, are the result of an EPA **review** aimed at "leveling the playing field," which means assuring that all states have essentially identical...
... FCAA recordkeeping and other requirements, which is commonly July 31, 1992.

Because of the urgent **deadline** for **approval** of these regulations, the TACB is conducting four public hearings:
--essentially concurrent hearings on March...

6/6,K/92 (Item 1 from file: 813)

0458524 c2903
COURT GRANTS PRICE WATERHOUSE EXTENSION OF DATE TO RECEIVE OFFERS TO PURCHASE BARGAIN HAROLD'S

DATE: March 24, 1992
WORD COUNT: 139

March 24 /CNW/ - Price Waterhouse, the court-appointed receiver, was today granted court **approval** to extend to 5 p.m. March 30 the **deadline** for accepting offers to purchase Bargain Harold's Discount Limited.

The **deadline** extension was sought to allow several interested parties to **review** the business in more detail, said Larry Huizingh, Senior Vice-President of Price Waterhouse.

"Our...
?

R6

11/9,K/2 (Item 1 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

04199688 Supplier Number: 46141265 (THIS IS THE FULLTEXT)

KASSEBAUM, BLILEY SCHEDULE FEBRUARY FDA REFORM HEARINGS

Food Chemical News, v37, n51, pN/A
Feb 12, 1996
ISSN: 0015-6337
Language: English Record Type: Fulltext
Document Type: Newsletter; Trade
Word Count: 1837

TEXT:

Sen. Nancy Kassebaum (R-Kan.) and Rep. Tom Bliley (R-Va.) have scheduled hearings on overall reform of the Food and Drug Administration in late February, staffers for the Senate Labor and Human Resources Committee and the House Commerce Committee told a Feb. 7 Progress & Freedom Foundation meeting.

Kassebaum's hearings on her bill (S 1477) are scheduled for Feb. 21 and 22, with a hopeful eye toward a markup around March 15, committee staffer Jane Williams said (See FOOD CHEMICAL NEWS, Feb. 5, Page 28). Labor and Human Resources Committee Chairman Kassebaum sees S 1477 as a top priority, "something she is completely committed to," Williams noted of the retiring senator. The Senate FDA reform bill "offers the opportunity to fundamentally re-think what we're doing, how we're looking at questions of safety [when drug or device applications or food-additive petitions arrive at the FDA] ... and to have an overall vision of how products are reviewed and developed in this country," she added.

Commerce Committee Chairman Bliley, meanwhile, is expected to introduce his own FDA reform bill shortly and to hold hearings Feb. 27.

FDA alone cannot be blamed for the perceived current problems within the agency, Williams noted, adding that Congress "has not done a good job of holding regularly scheduled oversight hearings" to examine parts of the agency and/or the whole agency.

CVM, NCTR Oversight Hearings Slated

To correct that past mistake, the House Government Reform and Oversight Committee plans oversight hearings for the Center for Veterinary Medicine and the National Center for Toxicological Research, among others, in 1996, Anne Marie Finley, a staffer for committee member Rep. Christopher Shays (R-Conn.), told the group. CVM and NCTR have "never been part of a general oversight hearing," she noted, adding: "It should be interesting."

Shays, the chairman of the Human Resources and Intergovernmental Affairs Subcommittee, recently produced a report, "The FDA Food Additive **Review** Process: Backlog and **Failure** to Observe Statutory **Deadline** ," which was **approved** by the full committee (See FOOD CHEMICAL NEWS, Jan. 8, Page 3). Finley said the report could become part of any related legislation but that has not happened yet. Shays is also interested in pushing for better FDA processes for nutraceuticals, functional foods and macroingredients such as the recently approved olestra, she noted.

However, Finley admitted that "industry has in some cases been complicitous in working with the agency on getting to Yes' when probably [their petition] should been rejected initially." Such petitions drive up the numbers of backlogged food-additive petitions, she added.

Meanwhile, at the Commerce Committee, "we get a lot of complaints about FDA - some are trivial and some are you can't believe this story' situations," staffer John Cohrssen said. The committee anticipates "robust discussions" about third-party review of drugs, biologics and food additives at its just-scheduled Feb. 27 hearing, he noted, adding that he is "very appreciative of FDA reform ideas ... trucks [full of them] pull up every day!"

Cohrssen noted that new Sen. Ron Wyden (D-Ore.), who is filling the seat of former Sen. Robert Packwood (R-Ore.) after a January special election, had introduced HR 1742, an FDA reform bill, in the House. Now that he is in the Senate, he is likely to work with Kassebaum on her bill,

but, Cohrssen said jokingly, if he introduces his own bill, it can be called the "Wyden-Wyden bill." Wyden's Senate term lasts through 1998.

Commerce Committee member Christopher Cox (R-Calif.), who also is a member of the Oversight and Investigations Subcommittee (whose chairman, Rep. Joe Barton, has been active in FDA reform), is interested in fundamental change of the FDA, his staffer Tom Deusterberg said. As part of agency reform, he added, Cox wants: the "de-monopolization" of FDA; a speeding up of the regulatory review process (most likely through institutional change); better dissemination of information within the agency and from the agency to industry and other affected parties; international harmonization of regulatory procedures; and a change in the "antagonistic culture" of FDA.

Ted Kennedy Strongly Supports' FDA Reform; Holcombe Has Questions About 3rd Party Review

Sen. Ted Kennedy (D-Mass.) "strongly supports responsible, bipartisan reform" of FDA in this Congress, staffer David Nexon said. Kennedy is a long-time member of the Labor and Human Resources Committee. But, Nexon pointed out, the ideas advanced by critics of the FDA for sweeping reform are out of date and based on FDA problems that were in place "five or 10 years ago."

A "huge effort" at fundamental reform could result in throwing out a "base of expertise" at FDA that would not be beneficial to anyone, Nexon added, noting that Kennedy believes "such legislation will not pass." Kennedy is interested in seeing FDA: eliminate unnecessary regulation; eliminate export burdens for U.S. companies; speed up the approval processes; and move forward in efforts to allow pre-approval of drugs.

Adding to the Democratic side of the issue, Kay Holcombe, staffer for Rep. John Dingell (D-Mich.), said one of the problems about FDA reform is that "we've all been assigning blame and now is the time to stop that and work together." She added: "If Congress wants to reform FDA, we can do it, and we don't have to make excuses or arguments."

A former FDA official, she noted that "changing the fundamental structure of regulation under the Federal Food, Drug, and Cosmetic Act is a very difficult project." She said she had a few questions to raise about reform ideas propounded by Republicans. For example, while she agreed that third-party review of drug and food additive petitions is a "very good idea," she asked, "Who and where are these third parties? Are there that many academics just lusting to do third-party reviews?"

Also, "How do we know that third-party panels will be faster than FDA?" Holcombe noted, adding: "Our consumers are different from other consumers. We expect everything to be perfect and, if it's not, we're not happy about it." Resolution of potential conflict-of-interest problems raises another question, as does the projected situation of FDA having responsibility for compliance and enforcement efforts over products that FDA did not initially review (ones that are approved by a third-party panel), she said, wondering if FDA personnel might be reluctant to do so.

Henry Miller, co-author of a Progress & Freedom Foundation report released at the meeting - "Advancing Medical Innovation: Health, Safety and the Role of Government in the 21st Century" - told Nexon and Holcombe that there are "many [qualified] people willing to do third-party panels." The University of California at San Francisco recently let go a number of clinical-trial scientists because of a lack of funds, he pointed out, and they would be likely to jump at the chance to serve on a panel. A number of other academic institutions are cutting back these days, he added, and could be a source of panelists as well.

Burr Introduces Bill to Amend FFDCA to Revise Drug Scientific Information Dissemination

Rep. Richard Burr (R-N.C.) on Feb. 1 introduced HR 2932 to amend the FFDCA to revise the requirements of the act relating to the dissemination of scientific information on drugs. Rep. Charles Stenholm (D-Texas), a member of the Agriculture Committee and former chairman of that committee's livestock subcommittee, noted his support for the Burr bill, saying HR 2932 "would allow the holder of an approved new drug application to provide health professionals a reprint of a medical journal article that includes

information about the drug that is not in the FDA- approved package insert."

Senate Version of Farm Bill Contains Provisions for Redirecting Funds For Food Safety Research

The Senate version of the farm bill contains a provision stating that the secretary of Agriculture may transfer up to 5% of any amounts made available to a USDA agency responsible for food safety, animal or plant health to a USDA agency reporting to the under secretary of agriculture for research, education and economics "for the purpose of addressing imminent or emerging threats to food safety and animal and plant health." The bill notes that one of the purposes of federally supported agricultural research, extension and education is to improve risk management in the U.S. agriculture industry.

The bill also allows the USDA secretary to "establish and award grants for projects for a multi-year research initiative on human nutrition intervention and health promotion." The projects are supposed to specifically emphasize coordinated longitudinal research assessments of nutritional status and the implementation of unified, innovative intervention strategies that would identify and solve problems of nutritional inadequacy and contribute to the maintenance of health, well-being, performance and productivity of individuals, thereby reducing the need of the individuals to use the U.S. health care system and social programs.

The Agricultural Research Service administrator would administer the grants' funds in order to ensure a coordinated approach to health and nutrition research efforts. The appropriations for the grants would be authorized for fiscal years 1996 through 2002.

A related part of the Senate bill would authorize the secretary of agriculture to ask the National Academy of Sciences to conduct a study of the ARS role and mission. The study is supposed to: evaluate the strength of ARS science and its relevance to national priorities; examine how ARS work relates to the capacity of the U.S. agricultural research, education and extension system overall; and include recommendations, as appropriate. The secretary has 18 months after the NAS study is completed to prepare a report that describes the study and submit the report to the House and Senate Agriculture Committees.

Senate Tea Board Bill Passes; No House Counterpart Is Brewing Yet

The Senate has voted to dump the Board of Tea Examiners, but no similar bill has been introduced in the House, AP reported. The board, created in 1897, consists of one full- time FDA employee and six outside experts. They meet for two days each year in a Brooklyn warehouse to sample teas from all over the world to determine which are of sufficient quality to drink and thereby get onto the U.S. market.

The board costs less than $200,000 to operate annually, but bill cosponsor Sen. Harry Reid (D-Nev.) said it wasn't the cost, it's the fact that "we don't have a coffee board or a candy board. We do not need this tea board." An earlier attempt to get rid of the board occurred when such a measure was added to the 1996 spending bill for the FDA; but in the final bill, the tea board was not eliminated.

Antimicrobial Pesticide Bill Support Urged; Measure May Be Incorporated into HR 1627

Sens. Rod Grams (R-Minn.) and Howell Heflin (D-Ala.) have written senators urging them to support the Antimicrobial Pesticide Registration Reform Act of 1995 (S 1491) (See FOOD CHEMICAL NEWS, Feb. 5, Page 28).

Chemical Specialties Manufacturers Association President Ralph Engel told our sister publication, PESTICIDE & TOXIC CHEMICAL NEWS, that industry intends to incorporate the bill into a Senate food safety bill as sooon as one is introduced and also plans to incorporate it into HR 1627, the Food Quality Protection Act.

PUBLISHER NAME: Food Chemical News, Inc.
EVENT NAMES: *970 (Government domestic functions)
GEOGRAPHIC NAMES: *1USA (United States)

PRODUCT NAMES: *9124230 (Food & Drug Administration)
INDUSTRY NAMES: BUSN (Any type of business); CHEM (Chemicals, Plastics and Rubber); FOOD (Food, Beverages and Nutrition)
NAICS CODES: 92614 (Regulation of Agricultural Marketing and Commodities)

... the Human Resources and Intergovernmental Affairs Subcommittee, recently produced a report, "The FDA Food Additive **Review** Process: Backlog and **Failure** to Observe Statutory **Deadline** ," which was **approved** by the full committee (See FOOD CHEMICAL NEWS, Jan. 8, Page 3). Finley said the...

R2

Articles 1995

(V)

11/9,K/1 (Item 1 from file: 15)
DIALOG(R)File 15:ABI/Inform(R)

01032500 96-81893

What's really the matter with FDA

Wechsler, Jill

Pharmaceutical Executive v15n5 PP: 20-24 May 1995 ISSN: 0279-6570
JRNL CODE: PHX
DOC TYPE: Journal article LANGUAGE: English LENGTH: 3 Pages
WORD COUNT: 2285

ABSTRACT: With a number of House and Senate committees holding hearings on FDA programs and policies, numerous trade associations, research institutes, and experts in the pharmaceutical field are busy developing "wish lists" for reform, most of which FDA could implement without new legislation - if the agency was so inclined. Louis Lasagna, director of the Center for the Study of Drug Development at Tufts University, summed up FDA's problems at a recent seminar about FDA reform, including: 1. Review times are too long, particularly for supplemental new-drug applications. 2. Parts of the review should be privatized, and the agency should trust summary presentations instead of reanalyzing clinical data from sponsors. 3. Policy differences among FDA divisions prevent early and continuing collegial discussions between the regulators and the regulated, and sponsors need a better appeal mechanism.

(-)

TEXT: As Congress begins to examine complaints about excessive FDA regulation, the critics are singing a new refrain. Forget about too-long review times. The real problem is the ever-lengthening requirements for testing and developing new therapies, plus restrictions on information and communications. FDA says that with the help of user fees it can speed up the review process, and it probably can. That won't bring new therapies to market faster, though, if regulators keep issuing new research demands and restrict company-sponsored promotion and education. The growing consensus is that only congressional action--and not internal fine-tuning of FDA practices-will alter the risk--averse mentality at FDA. Industry's enthusiasm for FDA deregulation, however, may be offset by its desire to point to a strong regulatory system as justification for curbing product liability exposure-another reform measure that Republicans are pursuing with vigor.

With a number of House and Senate committees holding hearings on FDA programs and policies (see Washington Report, March 1995), numerous trade associations, research institutes, and experts in the field are busy developing "wish lists" for reform, most of which FDA could implement without new legislation--if the agency was so inclined. Louis Lasagna, director of the Center for the Study of Drug Development at Tufts University, summed up FDA's problems at a recent seminar about FDA reform that the American Enterprise Institute (AEI) sponsored: Review times are too long, particularly for supplemental new-drug applications (NDAs). Parts of the review should be privatized, and the agency should trust summary presentations instead of reanalyzing clinical data from sponsors. Policy differences among FDA divisions prevent "early and continuing collegial discussions" between the regulators and the regulated, and sponsors need a better appeal mechanism. FDA should allow the export of products to countries where they are already approved, reduce clinical holds, and stop reviewing the hundreds of noncommercial investigational new-drug applications (INDs) that physician investigators file each year.

Lasagna also had a few complaints about FDA regulation of labeling and promotion. Drug labeling is out-of-date, partly because it omits indications that experts judge to be "perfectly acceptable." Even though physicians are free to read articles in peer-reviewed journals on new uses of a drug, sponsors are forbidden to distribute such information.

Most of those suggestions have surfaced before. Expert committees have been sounding the "drumbeat of recommendations for regulatory relief' since Congress expanded the Food and Drug Law in the sixties, pointed out William Wardell, president of Protein Engineering Corp. Instead of fine-tuning the FDA approval process, Wardell wants to address the IND bottleneck in the drug development process. What is needed is a very rapid screening process that allows sponsors to drop failures quickly, coupled with authority for outside review boards to approve early clinical research.

"We need to look at the time before the NDA is submitted--that's where the real cost is incurred," says Washington attorney and former FDA counsel Peter Barton Hutt. His list of FDA reforms is quite similar to Lasagna's, but he believes that FDA will fail to make the changes unless Congress requires it to do so. Despite hundreds of reports and recommendations since 1939, FDA "has done zilch," he told the AEI meeting. "Every time there's a new commission report, the agency tinkers a little with the system. What we need is mandatory, brutally intrusive legislation that demands reform. The last such effort in 1979-80 produced a too-long 300-page bill that everyone dismissed," Hutt recalls. Taking a cue from that and last year's health reform debate, he now recommends a short, concise, targeted measure. In addition to addressing basic reforms, he would like to shift the NDA approval to the end of Phase II in the drug development process and have Phase In research fall into the postapproval phase. That change, he believes, would reduce the IND-NDA time frame by three to four years. To disseminate information about unapproved uses, he wants to create a new, small area on the label where manufacturers can list unapproved uses and cite a handful of peer-review articles that support them.

BUILDING UP THE DEFENSE

FDA officials are promising to make changes, but more likely to head off the reformers than to alter practices. Last March, FDA joined the White House in announcing several relatively easy reforms as part of the Clinton administration's "Reinventing Government" initiative. Besides modifications in the regulation of noncritical medical devices, FDA said it would no longer require preapproval of certain changes to manufacturing processes for drugs and biologicals. The plan would also eliminate special batch review of insulin and antibiotics, and it would drop the need for environmental assessments of new drugs, which invariably conclude that the product will have "no significant impact on the environment

FDA can implement most of those changes without new legislation, but the next round of reforms promises to be more difficult. Still to come are more changes in the review process that may require legislative action. Earlier comments from Kessler to a Senate Appropriations panel, however, revealed a strong hesitancy to make serious changes. He said that he's open to looking at any ideas where privatization makes sense. But he is concerned that such practices would be a "blatant conflict of interest" and would promote "forum shopping

In a similar tone, Bob Temple, director of the Office of Drug Evaluation I at the Center for Drug Evaluation and Research (CDER), refutes the charge that FDA's regulatory process is more stringent than Europe's or Japan's by pointing to the international harmonization effort, which levels the playing field. One major difference, he acknowledges, is that CDER looks at the data while Europeans rely on summaries, but he adds that the European practice might change as the European regulatory agency expands its staff. Temple also maintains that the user-fee program has brought about a "palpable change" in attitude at FDA. Reviewers no longer insist that they can do their job "right" or "fast"; today it's both right and fast.

Temple admits a need to avoid lengthy clinical holds and says he's troubled by industry's complaints about lack of recourse at the agency. But he is adamant about prohibiting manufacturers from advertising any unapproved uses: "It's unreasonable to expect that drug companies will provide a really well-balanced view."

FDA actions often speak louder than words. As the debate over FDA regulation of the drug development process continues, the agency is proposing new policies that would further lengthen and increase the cost of clinical research. One is FDA's proposed new policy on pediatric-drug labeling. Although it could increase information about prescription drugs for children, it may also place a significant burden on sponsors to gather additional clinical data.

Another challenge for drug developers arises from FDA efforts to encourage more research about pharmaceutical effects on women. The latest idea is to allow pregnant women to enter early clinical trials, based on the rationale that expectant mothers need to take medications. Researchers say that there are differences in how pregnant women absorb and metabolize certain medications, how drugs interact with other nutrients, and how drugs affect the fetus. Because sponsors are reluctant to include pregnant women in early trials, an alternative might be to launch broad studies on how various widely used medications affect pregnant women. Another suggestion is to complete animal testing for teratogenicity and mutagenicity before Phase I trials begin to make it safer to include pregnant women in the tests--a strategy that would only delay the start of clinical testing and lengthen the process of developing new drugs.

LIMITING LIABILITY

The key issue for the pharmaceutical industry is that including pregnant women in research could expose companies to lawsuits from test participants experiencing complications or birth defects--regardless of whether such an outcome is related to the test drug. Of course, if the Senate approves the landmark product liability reform legislation that the House enacted in March, it could mitigate some of those concerns. As a key part of the House Republican's "Contract with America," the legislators recently approved three bills. The first, and least likely to survive in the Senate, would curb "frivolous" lawsuits by requiring unsuccessful plaintiffs to pay their opponents' legal fees. The second aims to limit suits by disgruntled shareholders against public companies. The third is a far-reaching measure that would overhaul the rules governing product liability and medical malpractice cases at both the state and federal levels.

A key provision in the last bill is the "FDA defense" amendment, which would bar punitive damages in cases involving FDA-approved drugs and devices. An alliance of physicians, insurance companies, hospitals, and drug- and medical equipment makers succeeded in adding that measure, which Congressman Michael Oxley (R., Ohio) offered during the final debate. The bill was also amended to include provisions to reduce medical malpractice litigation, based on the idea that it will curtail the rise in health care costs. One widely debated measure would cap noneconomic damages such as pain and suffering at $250,000 in all state and federal actions involving doctors, hospitals, and health insurance companies. That cap of $250,000, or three times monetary damages, had been approved earlier for all state and federal civil cases, but the provision extends it explicitly to medical practices and products.

Somewhat unusual for Republicans, the bill would limit state authority and set national standards for a number of legal issues that have traditionally been state-controlled. For example, it would restrict the "joint and several" liability system in most states, which makes all parties liable for all damages. It also limits suits against manufacturers of products sold more than 15 years ago, except in cases of negligence, and it reduces damages to a plaintiff who is partly responsible for an injury because of alcohol or drug use. Sellers of products would be liable for manufacturers' errors only if the seller issued a false warranty or contributed to the injury.

The Senate will consider several versions of those liability bills over the next few months with an eye to voting on the issue by August. The House "loser pays" measure and the one limiting fraud suits against public companies are expected to face the most opposition, and the product liability bill may be watered down considerably to survive a filibuster by Senate Democrats. The final measure will also have to be moderate enough to overcome an expected veto from President Clinton. If even a more modest version of the House legislation is enacted, though, it would represent a landmark shift away from the increasing litigiousness of American society, particularly in the health care area.

One irony is that the legislation is emerging just as the court finally rejected the decades-old Bendectin case. After countless appeals and rulings, the Ninth U.S. Circuit Court of Appeals in San Francisco, California, ruled in January that the plaintiffs' evidence against Merrell Dow was not scientifically valid and that the evidence failed to refute published epidemiological studies concluding that Bendectin causes no birth defects. Of course, the ruling comes years after the manufacturer pulled the drug off the market and industry basically abandoned research related to birth control and pregnancy.

DEFENDING FDA

Another irony is that if product liability reform legislation is approved with the FDA defense provision, industry might decide it is disinclined to weaken the agency's regulatory authority very much. Conservative proposals for FDA deregulation routinely cite the nation's tort system as providing sufficiently strong incentives for manufacturers to produce safe products. In response to criticism from Democrats that the product liability reform bill contradicts Republican efforts to curb the regulatory process, Congressman Oxley maintained that the GOP merely wants to make FDA more efficient, without making it less effective.

What will it take to accomplish that goal? Instead of trying to enact legislation that makes many specific revisions in current law, University of Chicago economics professor Sam Peltzman suggests broad structural reform based on an automatic **approval deadline** policy. Hutt likes the idea of a "statutory hammer" that requires FDA to act on an application in 100 days or else the product is automatically approved, similar to the existing policy for INDs. Another proposal is to set a **deadline** of three months for FDA to **review** an application for a drug that the European Medicines Evaluation Agency has already **approved** ; if FDA **fails** to object before the **deadline** , the product is automatically **approved** .

That kind of radical change is needed, according to some FDA critics, because industry cannot resist the agency's ever-expanding power to block manufacturer introduction of new products. FDA officials know that companies will comply with its dictates about advertising and manufacturing out of fear of a slowdown in approvals or other retaliation. One way to solve that problem is to break up the agency into a product-approval arm and a separate unit that regulates manufacturing and marketing.
Although such ideas have appeared in conservative proposals, such as those from House Speaker Newt Gingrich's Progress and Freedom Foundation's Future of Medical Innovative Project, the odds remain low that Congress will enact them. What is more likely is that those proposals from the "far-right think tanks" and "extremists," as Congressman Ron Wyden (D., Oregon) described them in a recent Washington Post editorial, will spur approval of a more specific bill addressing some of the bottlenecks on Lasagna's list. Even Wyden, who has certainly played a role in encouraging aggressive enforcement and risk aversion at FDA, now supports reduced regulation of some devices and noncritical applications, reform of requirements for early trials, and use of private, third-party reviews to help entrepreneurs "save time and money If liberal Democrats support such changes, perhaps Congress will take some action. And if the new rules have teeth, together with

product liability reform they could go far in improving the climate for biomedical product development in the United States.

COMPANY NAMES:
FDA
GEOGRAPHIC NAMES: US

DESCRIPTORS: Pharmaceutical industry; Regulatory agencies; Federal legislation; Reforms
CLASSIFICATION CODES: 9190 (CN=United States); 8641 (CN=Pharmaceuticals industry); 4310 (CN=Regulation); 9550 (CN=Public sector)

...TEXT: University of Chicago economics professor Sam Peltzman suggests broad structural reform based on an automatic **approval deadline** policy. Hutt likes the idea of a "statutory hammer" that requires FDA to act on...

...automatically approved, similar to the existing policy for INDs. Another proposal is to set a **deadline** of three months for FDA to **review** an application for a drug that the European Medicines Evaluation Agency has already **approved** ; if FDA **fails** to object before the **deadline** , the product is automatically **approved** .

That kind of radical change is needed, according to some FDA critics, because industry cannot...

R3

3/94

W

11/9,K/8 **(Item 1 from file: 636)**
DIALOG(R)File 636:Gale Group Newsletter DB(TM)

02333170 Supplier Number: 44557459 (THIS IS THE FULLTEXT)

THE GEJDENSON BILL: ANSWER TO INDUSTRY'S PRAYERS?

Export Control News, v8, n3, pN/A
March 31, 1994
ISSN: 0896-0682
Language: English Record Type: Fulltext
Document Type: Newsletter; Trade
Word Count: 526

TEXT:

Passage of Sam Gejdenson's export control legislation marked up by the House Foreign Affairs subcommittee on international trade on March 10 would effect several reforms that industry groups have urged for years. From mandatory product decontrols to limits on unilateral controls to drastic reforms in encryption software controls, the bill would both eliminate current restrictions and make existing ones harder for the executive branch to maintain. The following is a brief summary of the bill's key provisions compared side-by-side with corresponding reform recommendations advanced by the Clinton administration.

EAA REFORM PROPOSALS: HOUSE BILL VS. ADMINISTRATION BILL. A SIDE-BY-SIDE COMPARISON.

Provision	Administration Bill	House Bill
Unilateral Controls	Unilateral controls would expire every 12 months but may be renewed by a report certifying that the controls meet at least one of four criteria.	Unilateral controls could be imposed for 180 days. If the executive branch wants to extend the controls beyond the deadline and has been unable to gain multilateral cooperation, it must submit a report to Congress, and Congress must approve the extension by a "fast-track" joint resolution.
License Processing	Would shorten the processing deadline by one-fourth, from 120 days to 90 days. Would allow the Commerce Department 9 days to reach initial decisions on submitted license applications. Would give referral agencies 30 days for **review** , with no extension.	Would shorten processing deadline by three-quarters, from 120 days 30 days. **Failure** to meet **deadline** would mean automatic **approval** . Would give the executive branch discretion as to how to meet the **deadline** .
Foreign Availability	Would expand grounds under which an exporter may petition for relief, allowing relief when foreign availability exists, and when the controls impose an unfair burden on industry.	Would give the executive branch the discretion to take one of two actions pursuant to a positive foreign availability determination: 1) Propose to relevant export control regime that the item be

		decontrolled; or 2) Propose multilateral export and import sanctions against the foreign entity deemed to be the source of foreign availability.
Controls on Mass-Market Encryption Software.	No Provision. The bill would leave in place current controls on mass-market software with encryption features.	Would require that mass-market software with encryption functions be treated as dual-use items and would limit grounds under which they may be controlled.
Proliferation Sanctions	Would take the following two measures to harmonize the missile and CBW sanctions laws: 1) Apply the sanctions trigger in the existing CBW sanctions to the missile sanctions; and 2) Insert the export ban of the missile sanctions into the CBW sanctions.	Would authorize a broader set of sanctions for missile and CBW violations and extend sanctions to illicit nuclear trade as well. Would harmonize both the conditions that trigger the sanctions and the sanctions themselves. Would create a higher threshold for triggering the sanctions: the foreign entity must make a material contribution to the efforts of a proliferant country to produce illicit weapons. Current threshold only requires that the entity engage in illicit trade.
Judicial Review	Would provide for limited review of executive branch actions under EAA.	Would provide for extensive EAA judicial review under the Administrative Procedures Act.

PUBLISHER NAME: Export Control News
INDUSTRY NAMES: BUS (Business, General); BUSN (Any type of business)

... one-fourth,	from 120 days to 90 days. Would allow the Commerce Department 9 days to reach initial decisions on submitted license applications. Would give referral agencies 30 days for **review** , with no extension.	from 120 days 30 days. **Failure** to meet **deadline** would mean automatic **approval** . Would give the executive branch discretion as to how to meet the **deadline** .
Foreign Availability	Would expand grounds under which an...	Would give the executive

?

```
?pause
?show files; ds
File  15:ABI/Inform(R) 1971-2003/Jun 16
         (c) 2003 ProQuest Info&Learning
File  16:Gale Group PROMT(R) 1990-2003/Jun 16
         (c) 2003 The Gale Group
File 148:Gale Group Trade & Industry DB 1976-2003/Jun 13
         (c)2003 The Gale Group
File 160:Gale Group PROMT(R) 1972-1989
         (c) 1999 The Gale Group
File 275:Gale Group Computer DB(TM) 1983-2003/Jun 16
         (c) 2003 The Gale Group
File 621:Gale Group New Prod.Annou.(R) 1985-2003/Jun 13
         (c) 2003 The Gale Group
File   9:Business & Industry(R) Jul/1994-2003/Jun 13
         (c) 2003 Resp. DB Svcs.
File  20:Dialog Global Reporter 1997-2003/Jun 16
         (c) 2003 The Dialog Corp.
File 476:Financial Times Fulltext 1982-2003/Jun 16
         (c) 2003 Financial Times Ltd
File 610:Business Wire 1999-2003/Jun 16
         (c) 2003 Business Wire.
File 613:PR Newswire 1999-2003/Jun 16
         (c) 2003 PR Newswire Association Inc
File 624:McGraw-Hill Publications 1985-2003/Jun 13
         (c) 2003 McGraw-Hill Co. Inc
File 634:San Jose Mercury  Jun 1985-2003/Jun 14
         (c) 2003 San Jose Mercury News
File 636:Gale Group Newsletter DB(TM) 1987-2003/Jun 12
         (c) 2003 The Gale Group
File 810:Business Wire 1986-1999/Feb 28
         (c) 1999 Business Wire
File 813:PR Newswire 1987-1999/Apr 30
         (c) 1999 PR Newswire Association Inc

Set     Items   Description
S1       5628   REVIEW? (10N) (DEADLINE OR (TERMINATING (5N) PERIOD))
S2       7144   APPROV? (10N) (DEADLINE OR (TERMINATING (5N) PERIOD))
S3        171   S1 AND S2
S4        125   RD (unique items)
S5        108   S4 NOT PY>2001
S6         92   S4 NOT PY>2000
S7     365822   IF (10N) FAIL?
S8          7   S6 AND S7
S9      15118   FAIL? (10N) (DEADLINE OR (TERMINATING (10N) PERIOD))
S10        10   S3 AND S9
S11         8   RD (unique items)
S12      7136   APPROV? (10N) DEADLINE
S13      5936   AUTOMATIC (10N) APPROV?
S14        40   S12 AND S13
S15     14521   REQUISITION
S16     94449   PURCHASE (10N) (REQUEST OR ORDER)
S17         0   S14 AND S15
S18         0   S14 AND S16
S19         3   S12 AND S15
S20        29   S12 AND S16
S21        41   AUTOMATIC (10N) APPROV? (10N) DEADLINE
S22         0   S21 AND S15
S23         0   S21 AND S16
S24         3   S1 AND S21
S25        33   DEADLINE (10N) (AUTOMATIC (10N) APPROV?)
S26         0   S25 AND (S15 OR S16)
S27   7913315   REVIEW? OR APPROV?
S28        41   S21 AND S27
?logoff
       16jun03 14:27:41 User268136 Session D39.2
```

```
        $5.84    1.081 DialUnits File15
           $6.80  2 Type(s) in Format  9
           $5.20  20 Type(s) in Format 95 (KWIC)
       $12.00  22 Types
$17.84  Estimated cost File15
        $9.39    1.740 DialUnits File16
          $10.35  3 Type(s) in Format  9
          $13.00  50 Type(s) in Format 95 (KWIC)
       $23.35  53 Types
$32.74  Estimated cost File16
       $12.68    2.349 DialUnits File148
           $7.28  28 Type(s) in Format 95 (KWIC)
        $7.28  28 Types
$19.96  Estimated cost File148
        $1.29    0.239 DialUnits File160
           $0.26  1 Type(s) in Format 95 (KWIC)
        $0.26  1 Types
 $1.55  Estimated cost File160
        $2.28    0.421 DialUnits File275
           $1.40  2 Type(s) in Format 95 (KWIC)
        $1.40  2 Types
 $3.68  Estimated cost File275
        $5.11    0.947 DialUnits File621
           $1.04  4 Type(s) in Format 95 (KWIC)
        $1.04  4 Types
 $6.15  Estimated cost File621
        $3.23    0.599 DialUnits File9
           $0.78  3 Type(s) in Format 95 (KWIC)
        $0.78  3 Types
 $4.01  Estimated cost File9
        $3.77    3.775 DialUnits File20
           $8.85  3 Type(s) in Format  9
           $0.00  34 Type(s) in Format 95 (KWIC)
        $8.85  37 Types
$12.62  Estimated cost File20
        $0.47    0.471 DialUnits File476
           $3.90  3 Type(s) in Format 95 (KWIC)
        $3.90  3 Types
 $4.37  Estimated cost File476
        $0.39    0.392 DialUnits File610
 $0.39  Estimated cost File610
        $0.49    0.488 DialUnits File613
           $0.00  4 Type(s) in Format 95 (KWIC)
        $0.00  4 Types
 $0.49  Estimated cost File613
        $3.06    0.542 DialUnits File624
           $7.00  2 Type(s) in Format  9
           $0.00  15 Type(s) in Format 95 (KWIC)
        $7.00  17 Types
$10.06  Estimated cost File624
        $0.50    0.503 DialUnits File634
           $2.95  1 Type(s) in Format  9
           $0.00  5 Type(s) in Format 95 (KWIC)
        $2.95  6 Types
 $3.45  Estimated cost File634
        $7.46    1.382 DialUnits File636
          $10.35  3 Type(s) in Format  9
           $0.00  47 Type(s) in Format 95 (KWIC)
       $10.35  50 Types
$17.81  Estimated cost File636
        $0.43    0.435 DialUnits File810
           $0.00  1 Type(s) in Format 95 (KWIC)
        $0.00  1 Types
 $0.43  Estimated cost File810
        $0.40    0.401 DialUnits File813
           $0.00  1 Type(s) in Format 95 (KWIC)
```

```
          $0.00  1 Types
     $0.40  Estimated cost File813
            OneSearch, 16 files, 15.764 DialUnits FileOS
    $17.72  TELNET
   $153.67  Estimated cost this search
   $153.77  Estimated total session cost  15.921 DialUnits


### Status: Signed Off. (76 minutes)
```

```
PLEASE ENTER A COMMAND OR BE LOGGED OFF IN 5 MINUTES
?pause
?show files; ds
File  15:ABI/Inform(R) 1971-2003/Jun 16
         (c) 2003 ProQuest Info&Learning
File  16:Gale Group PROMT(R) 1990-2003/Jun 16
         (c) 2003 The Gale Group
File 148:Gale Group Trade & Industry DB 1976-2003/Jun 13
         (c)2003 The Gale Group
File 160:Gale Group PROMT(R) 1972-1989
         (c) 1999 The Gale Group
File 275:Gale Group Computer DB(TM) 1983-2003/Jun 16
         (c) 2003 The Gale Group
File 621:Gale Group New Prod.Annou.(R) 1985-2003/Jun 13
         (c) 2003 The Gale Group
File   9:Business & Industry(R) Jul/1994-2003/Jun 13
         (c) 2003 Resp. DB Svcs.
File  20:Dialog Global Reporter 1997-2003/Jun 16
         (c) 2003 The Dialog Corp.
File 476:Financial Times Fulltext 1982-2003/Jun 16
         (c) 2003 Financial Times Ltd
File 610:Business Wire 1999-2003/Jun 16
         (c) 2003 Business Wire.
File 613:PR Newswire 1999-2003/Jun 16
         (c) 2003 PR Newswire Association Inc
File 624:McGraw-Hill Publications 1985-2003/Jun 13
         (c) 2003 McGraw-Hill Co. Inc
File 634:San Jose Mercury  Jun 1985-2003/Jun 14
         (c) 2003 San Jose Mercury News
File 636:Gale Group Newsletter DB(TM) 1987-2003/Jun 12
         (c) 2003 The Gale Group
File 810:Business Wire 1986-1999/Feb 28
         (c) 1999 Business Wire
File 813:PR Newswire 1987-1999/Apr 30
         (c) 1999 PR Newswire Association Inc

Set      Items   Description
S1        5628   REVIEW? (10N) (DEADLINE OR (TERMINATING (5N) PERIOD))
S2        7144   APPROV? (10N) (DEADLINE OR (TERMINATING (5N) PERIOD))
S3         171   S1 AND S2
S4         125   RD (unique items)
S5         108   S4 NOT PY>2001
S6          92   S4 NOT PY>2000
S7      365822   IF (10N) FAIL?
S8           7   S6 AND S7
S9       15118   FAIL? (10N) (DEADLINE OR (TERMINATING (10N) PERIOD))
S10         10   S3 AND S9
S11          8   RD (unique items)
S12       7136   APPROV? (10N) DEADLINE
S13       5936   AUTOMATIC (10N) APPROV?
S14         40   S12 AND S13
S15      14521   REQUISITION
S16      94449   PURCHASE (10N) (REQUEST OR ORDER)
S17          0   S14 AND S15
S18          0   S14 AND S16
S19          3   S12 AND S15
S20         29   S12 AND S16
S21         41   AUTOMATIC (10N) APPROV? (10N) DEADLINE
S22          0   S21 AND S15
S23          0   S21 AND S16
S24          3   S1 AND S21
S25         33   DEADLINE (10N) (AUTOMATIC (10N) APPROV?)
S26          0   S25 AND (S15 OR S16)
S27    7913315   REVIEW? OR APPROV?
S28         41   S21 AND S27
?
```